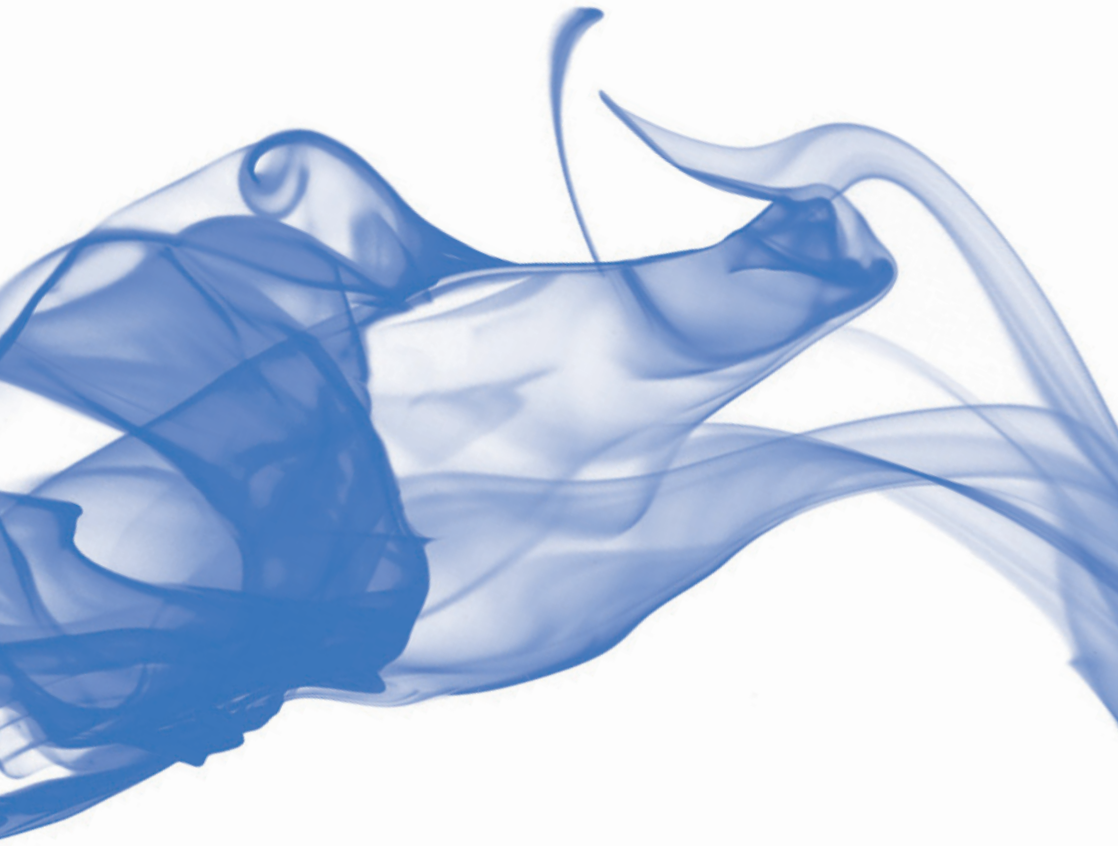
GE Healthcare

Nuclear medicine product catalogue



Prescribing information is available at the back of this catalogue.
Some products will not be available in all countries.

INTRODUCTION

Since the advent of nuclear medicine and molecular imaging in the 1950s, GE Healthcare has been at the forefront of innovation in diagnostic, therapeutic and research tools for healthcare professionals. Nuclear medicine allows us to assess organ function as well as structure, marking a new dawn in understanding disease at complex levels without the use of invasive procedures. The company's growing portfolio of products can detect pathological changes even at a molecular level.

This brochure provides an overview of the key diagnostic and therapeutic tools that are currently available in the fields of oncology, neurology and cardiology, as well as products for the rest of the body. Reference should be made to full national SPCs for precise product information.

GE Healthcare is dedicated to constantly adapting and innovating the best technology and equipment, and is always looking to the future by building on its current portfolio of products. We pride ourselves in working with healthcare professionals in order to understand all diseases, and are particularly committed to the recognition of early diseases. We are committed to continuing development and research of our current products as well as looking for novel compounds that can contribute to the revolutionary field of nuclear medicine.

CONTENTS

NANOCOLL

Nanocoll (^{99m}Tc albumin colloid kit)

Nanocoll is a diagnostic agent. It can be administered subcutaneously for lymphatic scanning to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction. It is indicated for use with lymphoscintingraphy and can be used, for example, in sentinel node mapping. It can also be administered intravenously for bone marrow scanning and inflammation scanning in areas other than the abdomen.

^{131}I mIBG Diagnostic and ^{131}I mIBG Therapy (Meta-Iodobenzylguanidine (^{131}I) for diagnostic and therapeutic use)

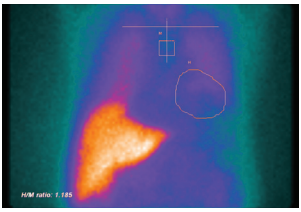
^{131}I mIBG comes as an injection for intravenous administration and can be used, at different dose levels, for diagnostic and therapeutic purposes. It is used in the identification and radiation therapy of tumour tissue that is capable of retaining iobenguane. These are tumours arising from cells originating embryologically from the neural crest, and include: pheochromocytomas, neuroblastomas, carcinoids and medullary carcinomas of the thyroid gland.

Metastron (strontium-89 chloride)

This intravenously administered radioisotope provides palliation from bone pain in patients with bone metastases secondary to prostate cancer at the stage of hormone therapy failure. The active agent, strontium-89, is a calcium analogue, which targets areas of calcium uptake, including growing bone cancer.

AdreView™
Iobenguane I 123 Injection

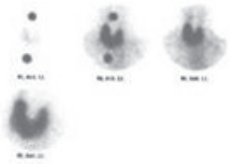
AdreView (^{123}I iobenguane)



AdreView can be used as an intravenous injection with scintigraphy to localise tumours that stem from the neural crest and for detection, staging and follow up of neuroblastomas. AdreView also assesses myocardial sympathetic innervation.

THERACAP 131™
(Natriumiodid [^{131}I] Therapiekapseln)

Theracap (sodium iodide-131)



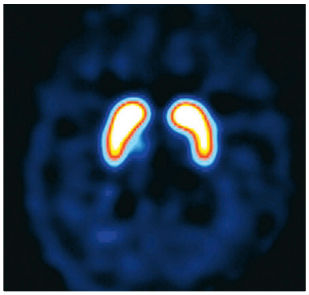
This is a capsule formulation of the iodine radioisotope that can be used to treat tumours in the thyroid gland. It can also be used in the treatment of Grave's disease, toxic multinodular goitre or autonomous nodules.

Steripet (^{18}F fludeoxyglucose)

SteriPET contains a ^{18}F-fludeoxyglucose that collects in diseased or cancerous areas or organs of the body, where there is an increase in glucose concentration. When SteriPET is injected intravenously, it is taken up by the body in the same way as glucose. The product can be used to diagnose, stage, monitor therapeutic response and detect cancer recurrences in, for example, the digestive system, ovaries, head and neck, lungs, bones and breast.

DaTSCAN™
IOFLUPANE (^{123}I)

DaTSCAN (^{123}I ioflupane)



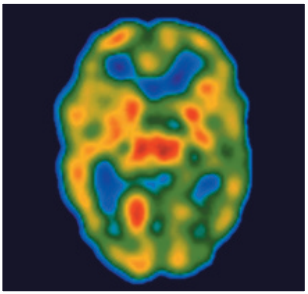
DaTSCAN is an imaging agent with selective affinity for presynaptic dopamine transporters (DaT). It is used to visualise level of dopaminergic loss, aiding differentiation between probable dementia with Lewy bodies (when dopamine transport is significantly reduced) and Alzheimer's Disease (when it is not). DaTSCAN is also indicated to help differentiate Essential Tremor from Parkinsonian Syndromes.

^{123}I IBZM Injection (^{123}I iolopride)

^{123}I IBZM combines an antipsychotic drug (iolopride) and a labelling agent (iodine-123). The product can specifically bind to postsynaptic dopamine D2 receptors in striatal neurones. The injection is intravenously administered and, together with SPECT imaging, helps to determine the blocking of receptors during treatment with neuroleptics.

Ceretec™

Kit for the preparation of Technetium [^{99m}Tc] Exametazime Injection



Ceretec (^{99m}Tc exametazime)

Ceretec is an imaging agent labelled with technetium-99m. It can be administered as an intravenous injection for scintigraphy of abnormalities of regional cerebral blood flow after stroke or other cerebrovascular disease, epilepsy, Alzheimer's disease, some forms of dementia, transient ischaemic attack, migraine, and tumours of the brain. It can also be used for in vitro 99mTc-leucocyte labeling, where labeled leucocytes are re-injected for scintigraphic imaging to localise intra-abdominal infection and inflammatory bowel disease.

Stabilised Ceretec™

Kit for the preparation of Technetium [^{99m}Tc] Exametazime Injection

Ceretec (^{99m}Tc exametazime)

Stabilised Ceretec is an imaging agent labelled with technetium-99m. It can be administered as an intravenous injection for scintigraphy of abnormalities of regional cerebral blood flow after stroke or other cerebrovascular disease, epilepsy, Alzheimer's disease, some forms of dementia, transient ischaemic attack, migraine, and tumours of the brain.

MYOVIEW™
(KIT FOR THE PREPARATION OF TECHNETIUM [^{99m}Tc] TETROFOSMIN)

Myoview (^{99m}Tc tetrofosmin)

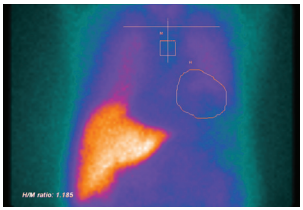
Myoview is a technetium-99m-labelled agent that can be used with scintigraphy or SPECT imaging of the heart, in particular the myocardium, during both exercise and rest. Myoview can diagnose myocardial ischaemia or infarction and, importantly, can localise the abnormality. Myoview can also be used to identify changes in perfusion induced by pharmacological stress in patients with known or suspected coronary artery disease, as well as assessment of left ventricular function in patients with heart disease.

Rapiscan
regadenoson

Rapiscan (regadenoson)

Rapiscan, administered as a non-weight-based bolus injection, is a pharmacological stress agent for myocardial perfusion imaging used in the diagnosis of coronary artery disease in adults unable to undergo adequate exercise stress testing. GE currently holds the exclusive distribution rights for UK and Germany only.

AdreView™
Iobenguane I 123 Injection



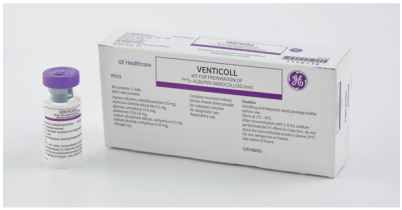
AdreView (^{123}I iobenguane)

AdreView can be used as an intravenous injection with scintigraphy to assess myocardial sympathetic innervation. AdreView can also be used to localise tumours that stem from the neural crest and for detection, staging and follow up of neuroblastomas.

OTHER THERAPY AREAS

LUNG

Venticoll
(^{99m}Tc human albumin)



Venticoll comes as a powder for nebuliser and aerosol administration and is used to assess bronchial function and pulmonary ventilation. In its radiolabelled form, the product can be used in scintigraphy of the lungs and diagnosis of pulmonary embolism in combination with perfusion studies. This method allows non-invasive pulmonary investigation of patients.

Macrotec
(^{99m}Tc albumin aggregates)

Macrotec is an imaging agent that can be used with scintigraphy to assess pulmonary function in adults and children. The product is particularly useful in the early detection of pulmonary emboli and for assessment of pulmonary circulation in patients with conditions such as pulmonary neoplasm, pulmonary tuberculosis, and emphysema.

MAAsol
(^{99m}Tc albumin macroaggregates)

MAAsol is an intravenously injected agent for use with imaging to assess pulmonary function. As with Macrotec, MAAsol allows assessment of pulmonary circulation. It is a potential companion diagnostic for use with Venticoll.

LIVER/GALL BLADDER

SeHCAT™
Tauroselcholic [^{75}Se] acid

SeHCAT (^{75}Se homocholic acid taurine)

Bile acids are produced in the liver and are important for the digestion and absorption of lipids in the small intestine. SeHCAT comes in the form of capsules and works by mimicking the action of natural bile salts without being metabolised. It is a taurine-conjugated bile acid analogue labelled with selenium-75 that can be used in the investigation of bile acid malabsorbtion and the measurement of bile acid pool loss. It may also be used in the assessment of ileal function, in the investigation of inflammatory bowel disease and chronic diarrhoea and in the study of entero-hepatic circulation.

Bridatec (^{99m}Tc mebrofenin)

The hepatobiliary system includes the liver, gall bladder and bile ducts—all organs that have important roles in the production, storage, transport and release of bile, which in turn is needed in digestion. Bridatec can be used with scintigraphy for assessment of hepatobiliary function.

OTHER THERAPY AREAS

THYROID

THERACAP 131™
(Natriumiodid [131I] Therapiekapseln)

Theracap (^{131}I sodium iodide)

This is a capsule formulation of the iodine radioisotope that can be used to treat patients who have an overactive thyroid or swelling due to an enlarged thyroid. It can also be used for the clinical management of tumours in the thyroid gland.

Sodium Iodide (^{131}I) Diagnostic-low strength

This is a capsule formation of the radioactive sodium iodide isotope that can be given to a patient to quantify and assess thyroid uptake; it can then be used to calculate the activity required for radioiodine therapy in each patient.

Sodium Iodide (^{131}I) Injection-treatment strength

This is a solution formulation to be made up into an injection for intravenous administration. This dose is suitable for treatment of an overactive thyroid, swelling due to an enlarged thyroid, and treatment of thyroid carcinomas.

Sodium Iodide (^{123}I) Injection

Iodine-123-labelled sodium iodide is a radioactive version of natural iodide-127, a substance needed for the synthesis of a thyroid hormone to control the metabolic state of nearly all tissues and organs in the body. The product comes in the form of both an injection and capsules and is used for assessment of various thyroid abnormalities.

LYMPHATIC SYSTEM

NANOCOLL

Nanocoll (^{99m}Tc albumin colloid kit)

Nanocoll is a diagnostic agent. It is administered intravenously for bone marrow scanning and inflammation scanning in areas other than the abdomen. It can also be administered subcutaneously for lymphatic scanning to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction.

KIDNEY

Chromium (^{51}Cr) EDTA (ethylenediaminetetraacetic acid)

Chromium EDTA is chemically stable and metabolically inert and is excreted exclusively by the kidneys, making it an accurate indicator of filtration rates of the kidney. Intravenous administration of this product allows physicians to assess kidney function.

OTHER THERAPY AREAS

CELL LABELLING/INJECTION

Ceretec (^{99m}Tc exametazime)

Ceretec can be used for labelling of white blood cells to localise intra-abdominal infection and inflammatory bowel disease. It can also be administered as an intravenous injection for scintigraphy of abnormalities of regional cerebral blood flow after stroke or other cerebrovascular disease, epilepsy, Alzheimer's disease, some forms of dementia, transient ischaemic attack, migraine, and tumours of the brain.

Sodium chromate (^{51}Cr)

Sodium chromate specifically labels red blood cells, and can indicate their volume in the body. The product can be used to diagnose disorders such as polycythaemias.

Indium (^{111}In) chloride

Indium-111 chloride is used to radiolabel derivatised proteins, which are subsequently administered intravenously for a variety of investigative purposes using appropriate imaging procedures. Indium-111 chloride is used extensively for the radiolabelling of monoclonal antibodies for the investigation of disease, and is also used as the radiolabelling ingredient in injectable preparations, such as indium-111-labelled proteins.

Indium (^{111}In) oxine

Indium-111 oxine is used for the *in vitro* radiolabelling of separated blood cells which are subsequently administered intravenously for a variety of investigative purposes using appropriate imaging/counting procedures. Indium-111 labelled leucocytes or granulocytes can be used to localise sites of focal infection, confirm bone infection after prosthesis, investigate pyrexia of unknown origin and evaluate inflammatory conditions not associated with infection, such as inflammatory bowel disease. Labelled thrombocytes can be used to determine platelet survival and biodistribution, and labelled erythrocytes help with the investigation of sites of gastrointestinal haemorrhage.

TECHNETIUM GENERATORS

DRYTEC
Technetium Generator

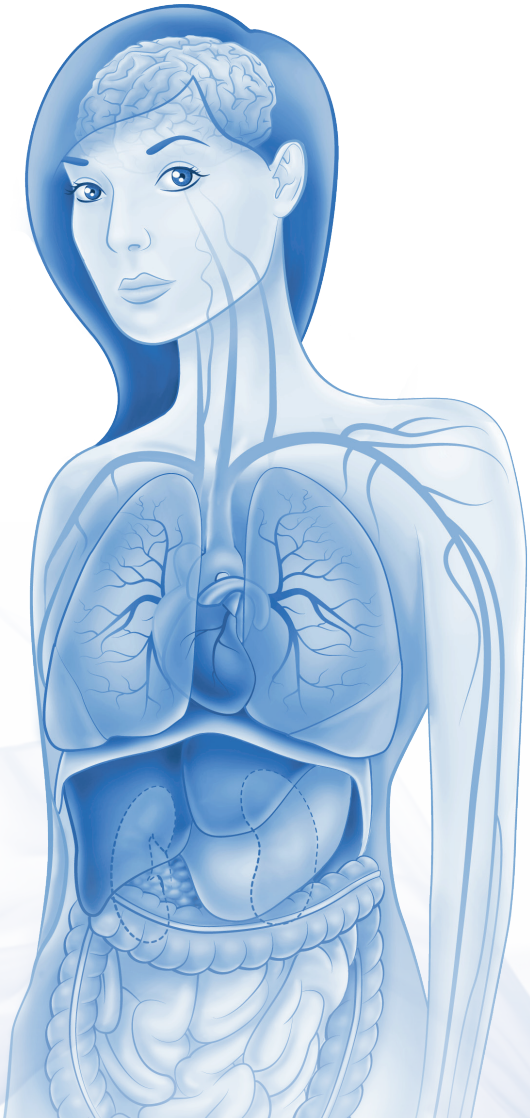
Drytec™ (^{99m}Tc pertechnetate generator)

GE Healthcare produces and supplies healthcare professionals with cold kits which can be labelled with sodium pertechnetate [^{99m}Tc].

Drytec is a sterile technetium-99m generator used to produce ^{99m}Tc pertechnetate injection in accordance with European Pharmacopoeia specifications for use *in vivo* or as a reagent for the labelling of compounds supplied as kits. Radioisotopes produced by Drytec can be used in scintigraphy of the thyroid, salivary glands, lacrimal duct, cerebrum, cardiac and vascular systems, location of ectopic gastric mucosa, and diagnosis and localisation of occult gastrointestinal bleeding.

NUCLEAR MEDICINE: THE FUTURE

GE Healthcare is dedicated to constantly adapting and innovating the best technology and equipment and is always looking to the future by building on its current portfolio of products.



PRESCRIBING INFORMATION

For all products listed here please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. Not all products hold a marketing authorisation in the UK but are available in other EU markets.

Contents list

PRESCRIBING INFORMATION [^{123}I]-IBZM Injection (Iolopride [I-123])

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. This product does not hold a marketing authorisation in the UK but is authorised in The Netherlands.

PRESENTATION ^{123}I-IBZM Injection is a clear, colorless to light brown, sterile, buffered solution for injection. Concentration of I-123 is 74 MBq/mL, 3.4 x 10^{-9} g/mL. **INDICATIONS** ^{123}I-IBZM is used for imaging of cerebral dopamine D2 receptor availability to determine the blocking of the receptors during treatment with neuroleptics. **DOSAGE AND METHOD OF ADMINISTRATION** ^{123}I-IBZM is administered by intravenous injection. The recommended dose for SPECT studies in adults is 185 MBq. Data collection can start at approximately 90 minutes after injection. **CONTRAINDICATIONS** No information is available on the effect/efficacy and harmfulness of ^{123}I-IBZM when administered to children. Therefore administration to children is contra-indicated. **WARNINGS AND PRECAUTIONS** Before administration it is recommended to block the thyroid with Lugol solution or with a saturated potassium iodide solution (100 g in 100 mL water), except for patients who are sensitive to iodine or iodine derivatives. Start with 10 drops of Lugol solution (or 3 drops saturated potassium iodide solution) 24 hours before administration of ^{123}I-IBZM and maintain the administration for 5 to 7 days. **INTERACTIONS** Medicinal products under the classification of neuroleptics, antipsychotics, dopamine agonists for treatment of Parkinson's disease except oral levodopa, drugs that enhance the availability of endogenous dopamine, calcium blockers and some anti-emetics with central dopaminergic action lower the striatal uptake of ^{123}I-IBZM. Domperidon does not affect the striatal uptake if the blood brain barrier is intact. **PREGNANCY AND LACTATION** In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. The absorbed dose for the uterus is 3.7 mGy when a 185 MBq is administered. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for three days and expressed feeds discarded. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** No undesirable effects were reported. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects (evidence suggests that these will occur with low frequency). **DOSIMETRY** The effective dose equivalent is 6.29 mSv for an adult (70 kg) when a standard dose of 185 MBq of ^{123}I-IBZM is administered. **MARKETING AUTHORISATION HOLDER** GE Healthcare B.V., Postbus 746, 5600 AS Eindhoven, Nederland. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **DATE OF REVISION OF TEXT** 31 August 2011

PRESCRIBING INFORMATION Sodium Iodide (^{123}I) Injection 37 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution for injection of sodium [^{123}I]iodide, 37 MBq/ml at reference date and hour. **INDICATIONS** Used as a diagnostic agent in the functional or morphological study of the thyroid gland by scintigraphy and radioactive iodine uptake test. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended activity for an adult patient (70 kg) is 3.7 14.8 MBq. The lower activity (3.7 MBq) is recommended for uptake studies and the higher doses (11.1-14.8 MBq) for thyroid scintigraphy, however the dose is decided for each individual case. The activity in children may be calculated from the recommended adult activity adjusted to body weight. Sodium Iodide (^{123}I) injection is administered intravenously; the activity in the injection should be measured immediately prior to administration. Imaging is performed 3-6 hours after administration. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** Particular care should be taken when administering radiopharmaceuticals to young persons, women of child bearing age and mothers who are breast feeding. Sodium Iodide (^{123}I) injection contains 3.99 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** Medicinal products can modify the uptake of iodine by the thyroid gland. These include amiodarone, antithyroid, lithium, natural or synthetic thyroid preparations, expectorants, vitamins, perchlorate, phenylbutazone, salicylates, steroids, sodium nitroprusside, sulfobromophtalein sodium, anticoagulants, antihistamines, antiparasitics, penicillins, sulfonamides, tolbutamide, thiopental, benzodiazepines, topical iodides, intravenous contrast agents, oral cholecystographic agents and oil-based iodinated contrast agents. **PREGNANCY AND LACTATION** In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for 1.5–3 days following the administration, and expressed feeds should be discarded. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with negligible frequency), allergic reactions (unknown frequency). Isolated cases of allergic reactions have been reported. **DOSIMETRY** The effective dose equivalent resulting from an administered activity of 14.8 MBq is 2.2 mSv. This is dependent on the uptake in the thyroid glands. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0138. **PRICE** Dependent on activity. For example 74 MBq £114.57. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Meta-Iodobenzylguanidine (^{131}I) for diagnostic use 9.25-18.5 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution for injection of [^{131}I]iobenguane 9.25-18.5 GBq/ml (0.05-0.5 mg/ml). **INDICATIONS** Used as a diagnostic agent. The sensitivity to diagnostic visualisation, and therefore also to therapeutic efficacy, is different for the listed pathologic entities. Pheochromocytomas and neuroblastomas are sensitive in approximately 90% of patients, carcinoids in 70% and medullary carcinomas of the thyroid gland (MCT) in only 35%. **DOSAGE AND METHOD OF ADMINISTRATION** Tracer dose to acquire dosimetric information is 20-40 MBq. Distribution measurement prior to administration of a therapeutic dose is recommended in order to establish the retention time of the radiopharmaceutical in organs, tumour tissue and normal structures. The recommended dosages are identical for children and adults. The dose is administered intravenously and the duration of the injection should be 30-300 seconds. **CONTRAINDICATIONS** Absolutely contraindicated in pregnancy and premature babies or neonates. Contraindicated in patients hypersensitive to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The product contains benzyl alcohol which may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old. Drugs that may interfere with uptake and retention of [^{131}I]iobenguane should be stopped before treatment. Emergency cardiac antihypertensive treatments should be readily available prior to administration. The uptake of iobenguane in the chromaffin granules might, though rarely, cause rapid noradrenalin secretion which can induce a hypertensive crisis although the likelihood of such an occurrence is believed to be extremely low. This necessitates constant monitoring of the patient during administration. Monitoring of both ECG and blood pressure during administration could be indicated in some patients. [^{131}I]iobenguane must be administered slowly. When diagnostic administration for pheochromocytoma is planned, attention should be given to the interference with uptake of [^{131}I]iobenguane by medication for control of hypertension. Incompatible medication should be stopped at least 2 weeks prior to the planned diagnostic administration. Patients are to be well hydrated. Blocking of the uptake of iodine-131 by the thyroid is recommended to reduce radiation dose. Blockade may be undertaken using non-radioactive iodine such as potassium iodide, potassium iodate or Lugol's solution. A daily dose of approximately 100 mg iodine should be administered which should commence 24-48 hours before [^{131}I]iobenguane is administered and should be continued for at least 5 days after its administration. In patients where the diagnostic evaluation shows diffuse bone marrow uptake of [^{131}I]iobenguane, bone marrow suppression may occur after administration of a therapeutic dose. This medicinal product contains less than 1 mmol sodium (23 mg) per maximum recommended dose, i.e. essentially 'sodium-free'. **INTERACTIONS** Nifedipine (a calcium channel blocker) is reported to prolong retention of iobenguane. Decreased uptake was observed under therapeutic regimens involving the administration of antihypertensive drugs such as reserpine, labetalol, calcium-channel blockers (diltiazem, nifedipine, verapamil), sympathomimetic agents (present in nasal decongestants, such as phenylephrine, ephedrine or phenylpropanolamine), cocaine, and tricyclic antidepressants (amitryptiline and derivatives, imipramine and derivatives, doxepin, amoxepine and loxapine). Antihypertensives acting through adrenergic neuron blockade (betanidine, debrisoquine, bretylium and guanethidine) and antidepressants such as maprotiline and trazolone may inhibit the uptake of iobenguane. All the above mentioned drugs should be stopped before treatment (usually for four biological half-lives). **PREGNANCY AND LACTATION** The product is contraindicated during pregnancy. Alternative techniques which do not involve ionising radiation should be considered. Any woman who has missed a period should be assumed to be pregnant. Investigation should be reasonably delayed until a mother has ceased breastfeeding. Breastfeeding should be discontinued after administration of the product. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with low frequency). **DOSIMETRY** The effective dose (ED) equivalent for an adult in normal pharmacokinetic behaviour is 0.2 mSv/MBq. The ED equivalent and the radiation dose delivered to organs (notably to bone, red marrow and lungs) might be increased considerably in renal impairment. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0124. **PRICE** Dependent on activity. For example 37 MBq £287.90. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Meta-Iodobenzylguanidine (^{131}I) for therapeutic use 185-740 MBq/ml solution for infusion or injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution for infusion or injection of [^{131}I]iobenguane 0.185-0.740 GBq/ml (not more than 0.67 mg/ml). **INDICATIONS** Radiation therapy of tumour tissue that is capable of retaining iobenguane. These are tumours arising from cells originating embryologically from the neural crest; pheochromocytomas, neuroblastomas, carcinoids and medullary carcinomas of the thyroid gland (MCT). **DOSAGE AND METHOD OF ADMINISTRATION** Therapeutic dose of [^{131}I]iobenguane is individually tailored on the basis of a dosimetric study. The size of the dose as well as the interval(s) between possible multiple administrations are mainly determined by haematological radio-toxicity and the kind of tumour. The more rapid the rate of progression of the tumour, the shorter the interval. The fixed dose is 3.7-7.4 GBq. These recommended dosages are identical for children and adults. No special dosage scheme is required for the elderly patient. The therapeutic dose is administered intravenously, generally as an infusion over a period of 1-4 hours. **CONTRAINDICATIONS** Absolutely contraindicated in pregnancy and premature babies or neonates. Contraindicated in patients hypersensitive to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The product contains benzyl alcohol which may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old. Normal tissue adjacent to the radiated cancer tissue may be damaged. Additive toxicity may occur in patients on chemotherapy. Children treated are at risk of developing irreversible thyroid function loss, growth retardation and hypergonadotropic hypogonadism; therefore special attention is paid to their endocrine status. Drugs that may interfere with uptake and retention of [^{131}I]iobenguane (several drugs used in hypertension and psychiatry) should be stopped before treatment. Thyroid blockade is started 24-48 hours before administration and continued for at least 5 days. Blockade is achieved by administration of potassium perchlorate, potassium iodide, potassium iodate or Lugol solution. Patients are to be well hydrated for at least the first 24 hours. [^{131}I]iobenguane therapy should be considered only in those patients where transplantation of autologous bone marrow (containing little or no tumour cells) is possible. The toxic effects on bone marrow (thrombocytopenia) must be monitored carefully and frequently. Blood counts are to be controlled every 2 days during the first week and later once a week for the month following the last administration. It is advisable to perform whole body scintigram for about 1 week in order to study the biodistribution of the agent and quantitate the uptake in tumour foci. Prior to administration, ensure emergency cardiac antihypertensive treatments are readily available. The uptake of iobenguane in the chromaffin granules might, though rarely, cause rapid noradrenalin secretion which can induce a hypertensive crisis although the likelihood of such an occurrence is believed to be extremely low. This necessitates constant monitoring of the patient during administration. Monitoring of both ECG and blood pressure during administration could be indicated in some patients. In patients where the diagnostic evaluation shows diffuse bone marrow uptake of [^{131}I]iobenguane, bone marrow suppression may occur after administration of a therapeutic dose. [^{131}I]iobenguane must be administered slowly. When the therapeutic administration for pheochromocytoma is planned, attention is to be given to possible interference between the medication for control of hypertension and the uptake of [^{131}I]iobenguane and incompatible medication should be stopped at least 2 weeks prior to the planned therapeutic administration. Dosages for patients with reduced renal function have to be adjusted accordingly. The main adverse reactions in children are thrombocytopenia (isolated) or bone marrow suppression, the more so if there is tumour infiltration in bone marrow. Women receiving [^{131}I]iobenguane should be advised not to become pregnant within at least 6-12 months of administration. This medicinal product contains 3.54 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** Nifedipine (a calcium channel blocker) is reported to prolong retention of iobenguane. Decreased uptake was observed under therapeutic regimens involving the administration of antihypertensive drugs such as reserpine, labetalol, calcium-channel blockers (diltiazem, nifedipine, verapamil), sympathomimetic agents (present in nasal decongestants, such as phenylephrine, ephedrine or phenylpropanolamine), cocaine, and tricyclic antidepressants (amitryptiline and derivatives, imipramine and derivatives, doxepin, amoxepine and loxapine). Antihypertensives acting through adrenergic neuron blockade (betanidine, debrisoquine, bretylium and guanethidine) and antidepressants such as maprotiline and trazolone may inhibit the uptake of iobenguane. All the above mentioned drugs should be stopped before treatment (usually for four biological half-lives). Special care must be given to the selection of anti-emetics that are often given to suppress the nausea that generally accompanies the administration of iobenguane in therapeutic quantities. Anti-emetics that are dopamine/serotonin receptor antagonists do not interfere with iobenguane uptake at concentrations as are used in clinical practice. **PREGNANCY AND LACTATION** The product is contraindicated during pregnancy. Alternative techniques which do not involve ionizing radiation should be considered. Any woman who has missed a period should be assumed to be pregnant. Investigation should be reasonably delayed until a mother has ceased breastfeeding and breastfeeding should be discontinued after administration of the product. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with low frequency). Increased infection susceptibility, leukaemias, malignant secondary cancers, bone marrow depression, anaemia, thrombocytopenia, neutropenia, hypothyroidism possibly leading to growth retardation in children and hyperthyroidism, salivary gland conditions, radiation injury (including radiation associated pain, interstitial lung disease, transient sialoadenitis, hypogonadism, and ovarian failure). Nausea and vomiting are very common.

DOSIMETRY The effective dose (ED) equivalent for an adult in normal pharmacokinetic behaviour is 0.2 mSv/MBq. The ED equivalent and the radiation dose delivered to organs (notably to bone, red marrow and lungs) might be increased considerably in renal impairment. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0125. **PRICE** Dependent on activity. For example 3.7 GBq £2207.82. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Sodium Iodide (^{131}I) 0.333-3.7 MBq Diagnostic Capsules

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION White, opaque, hard gelatin capsules of Sodium Iodide (^{131}I) containing 3.7 MBq (100 µCi) at the first reference date. **INDICATIONS** Used as a diagnostic agent to calculate the activity required for radioiodine therapy (tracer dose), to identify thyroid remnants and metastases (after ablation) in the management of thyroid carcinoma, and in thyroid scanning for benign conditions. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended activities for an adult (70 kg) for thyroid uptake studies are 0.2-3.7 MBq, for post thyroid ablation (metastases and thyroid remnant) a maximum dose of 400 MBq and for thyroid imaging 7.4-11 MBq. Scans are usually performed at 4 hours, and then again at 18-24 hours (for scintigraphy also at 72 hours). The activity in children over 10 years and adolescent can be calculated from the recommended adult dose adjusted to body weight or surface area. The capsules should be swallowed whole. In patients with suspected gastrointestinal disease the capsules should be taken with sufficient fluid to ensure clear passage into the stomach and upper small intestine. Concomitant use of H_2 antagonists or proton pump inhibitors is advised. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Pregnancy and for diagnostic purposes in children under 10 years. Thyroid scanning except in the follow-up of malignant disease or when iodine-123 or technetium-99m is not available. Patients with dysphagia, oesophageal stricture, active gastritis, gastric erosions and peptic ulcer. Patients with suspected reduced gastrointestinal motility. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. The therapeutic administration of sodium [^{131}I]iodide in patients with significant renal impairment requires special attention with regards to administered activity. Sperm banking should be considered for young men who have extensive disease and therefore may need high radioiodine therapeutic doses. Contraception for 6 months (for patients with benign thyroid conditions) or 12 months (for patients with thyroid cancer) is recommended for both sexes after therapeutic administration of sodium [^{131}I]iodide. Sodium Iodide (^{131}I) capsules contain 85.28 mg sodium per capsule; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** A full drug history should be taken and relevant medication should be withheld prior to administration, including the following: antithyroid agents, perchlorate, salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental, phenylbutazone, iodine expectorants and vitamins, thyroid hormone preparations, amiodarone, benzodiazepines, lithium, iodine preparations for topical use and iodine contrast media. **PREGNANCY AND LACTATION** Contraindicated in pregnancy. The absorbed dose to the uterus is likely to be in the range 11-511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters. Breast feeding should be discontinued after administration. It is recommended to avoid close contact between mother and child for at least one week. **UNDESIRABLE EFFECTS** Bone marrow depression, Sicca syndrome, endocrine ophthalmopathy, acquired dacryostenosis, nausea, vomiting, hypothyroidism, aggravated hyperthyroidism, Graves' disease, hyperparathyroidism, sialoadenitis, gastric cancer, leukaemia, bladder and breast cancer, hypersensitivity, radiation thyroiditis, impairment of fertility in men and woman and congenital thyroid disorders. **DOSIMETRY** The effective dose equivalent to an adult administered 3.7 MBq with 0% thyroid uptake is 0.27 mSv, with 15% thyroid uptake is 24.42 mSv, with 35% thyroid uptake is 55.5 mSv, and with 55% thyroid uptake is 88.8 mSv. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0112. **PRICE** 10 capsules £152.39. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Sodium Iodide (^{131}I) 74 MBq/ml and 925 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution for injection containing sodium [^{131}I]iodide, 37-740 MBq/vial (74 MBq/ml) and 0.925-9.25 GBq/vial (925 MBq/ml) at the activity reference date. **INDICATIONS** Used as a diagnostic agent to calculate the activity required for radioiodine therapy (tracer dose), in the management of thyroid carcinoma to identify thyroid remnant and metastases (after ablation) and in thyroid scanning for benign conditions. Therapeutic indications include treatment of Grave's disease, toxic multinodular goitre or autonomous nodules, and treatment of papillary and follicular thyroid carcinoma including metastatic disease. Therapy is often combined with surgical intervention and with antithyroid medications. **DOSAGE AND METHOD OF ADMINISTRATION** As a diagnostic agent the recommended activities for an adult patient (70 kg) are: for thyroid uptake studies 0.2-3.7 MBq, for post thyroid ablation (metastases and thyroid remnant) a maximum dose of 400 MBq, and for thyroid imaging 7.4-11 MBq. Scans are usually performed at 4 hours, and then again at 18-24 hours (for scintigraphy also at 72 hours). The administered activities for the treatment of hyperthyroidism is in the range of 200-800 MBq but repeated treatment may be necessary, with cumulative activities of up to 5000 MBq depending on the diagnosis, the size of the gland, thyroid uptake and iodine clearance. The administered activities following total or sub total thyroidectomy to ablate remaining thyroid tissue are in the range of 1850-3700 MBq. It depends on the remnant size and radioiodine uptake. In subsequent treatment for metastases, administered activity is in the range 3700-11100 MBq. After high doses used, e.g. for the treatment of thyroid carcinoma, patients should be encouraged to increase oral fluids to have frequent bladder emptying to reduce bladder radiation. The dose to be administered to a child over 10 years and adolescent can be calculated from the recommended adult dose adjusted to body weight and surface area. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Pregnancy and for diagnostic purposes in children under 10 years. Thyroid scanning except in the follow-up of malignant disease or when iodine-123 or technetium-99m is not available. Patients with dysphagia, oesophageal stricture, active gastritis, gastric erosions and peptic ulcer. Patients with suspected reduced gastrointestinal motility. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including anaphylactic and anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. The therapeutic administration in patients with significant renal impairment requires special attention. Sperm banking should be considered for young men who have extensive disease and therefore may need high radioiodine therapeutic doses. Contraception for 6 months (for patients with benign thyroid conditions) or 12 months (for patients with thyroid cancer) is recommended for both sexes after therapeutic administration. Sodium Iodide (^{131}I) injection contains 5.92 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** A full drug history should be taken and relevant medication should be withheld prior to administration, including the following: antithyroid agents, perchlorate, salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental, phenylbutazone, products containing iodine expectorants and vitamins, thyroid hormone preparations, amiodarone, benzodiazepines, lithium, products containing iodine preparations for topical use and iodine contrast media. **PREGNANCY AND LACTATION** Contraindicated in pregnancy. The absorbed dose to the uterus is in the range 11-511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters. Breast feeding should be discontinued after administration. It is recommended to avoid close contact between mother and child for at least one week after therapeutic dose. **UNDESIRABLE EFFECTS** Bone marrow depression, Sicca syndrome, endocrine ophthalmopathy, acquired dacryostenosis, nausea, vomiting, hypothyroidism, aggravated hyperthyroidism, Graves' disease, hyperparathyroidism, sialoadenitis, gastric cancer, leukaemia, bladder and breast cancer, hypersensitivity, radiation thyroiditis, impairment of fertility in men and woman and congenital thyroid disorders. **DOSIMETRY** The effective dose equivalent in an adult when administered 3.7 MBq with 0% thyroid uptake is 0.27 mSv, with 15% thyroid uptake is 24.42 mSv, with 35% thyroid uptake is 55.5 mSv and with 55% thyroid uptake is 88.8 mSv. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0113. **PRICE** Dependent on activity. For example 37 MBq £77.99. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION AdreView, 74 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Vials containing 74 MBq/ml Iobenguane (^{123}I) at calibration date and hour. Available pack size: 37 to 740 MBq. **DIAGNOSTIC INDICATIONS** • Diagnostic scintigraphic localisation of tumours originating in tissue that embryologically stems from the neural crest. These are pheochromocytomas, paragangliomas, chemodectomas and ganglioneuromas. • Detection, staging and follow-up on therapy of neuroblastomas. • Evaluation of the uptake of iobenguane. The sensitivity to diagnostic visualisation is different for the listed pathological entities. Pheochromocytomas and neuroblastomas are sensitive in approx. 90% of patients, carcinoids in 70% and medullary carcinoma of the thyroid (MCT) in only 35%. • Functional studies of the adrenal medulla (hyperplasia) and the myocardium (sympathetic innervation). **DOSAGE AND METHOD OF ADMINISTRATION** For adults the recommended dosage is 80-200 MBq, higher activities may be justifiable. Children under 6 months: 4 MBq per kg body weight (max. 40 MBq), the product must not be given to premature babies or neonates. Children between 6 months and 2 years: 4 MBq per kg body weight (min. 40 MBq). Children over 2 years: a fraction of the adult dosage should be chosen, dependent on body weight (see SPC for scheme). No special dosage scheme required for elderly patients. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Must not be given to premature babies or neonates. **WARNINGS AND PRECAUTIONS** This medicinal product contains benzyl alcohol. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old. Administer dose intravenously over several minutes. Monitor the patient constantly during administration as, in theory, iobenguane uptake in the chromaffin granules may induce a hypertensive crisis due to noradrenaline secretion. Image 24 and 48 hours after administration. Drugs known or expected to reduce the iobenguane(123-I) uptake should be stopped before treatment (usually 4 biological half-lives). Thyroid blockade is started 24-48 hours before the iobenguane(123-I) is administered and continued for at least 3 days. Blockade by potassium perchlorate is achieved by administration of approx. 400 mg/day. Blockade by potassium iodide, potassium iodate or Lugol solution must be performed with an equivalent of 100 mg of iodine/day. Radiopharmaceuticals should only be used by qualified personnel with appropriate government authorisation and should be prepared using aseptic and radiological safety requirements. **INTERACTIONS** Decreased uptake was observed under therapeutic regimens involving the administration of reserpine, labetalol, calcium-channel blockers (diltiazem, nifedipine, verapamil), tricyclic antidepressives (amitryptiline, imipramine and derivatives), sympathomimetic agents (present in nasal decongestants, such as phenylephrine, ephedrine or phenylpropanolamine), cocaine and phenothiazine. These drugs should be stopped before administration of iobenguane (^{123}I) (usually for four biological half-lives to allow complete washout). Nifedipine (a Ca-channel blocker) is reported to prolong retention of iobenguane. **PREGNANCY AND LACTATION** Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Only imperative investigations should be carried out during pregnancy, when likely benefit exceeds the risks incurred by mother and foetus. If administration to a breast feeding woman is necessary, breast-feeding should be interrupted for three days and the expressed feeds discarded. Breast-feeding can be restarted when the level in the milk will not result in a radiation dose to a child greater than 1 mSv. **UNDESIRABLE EFFECTS** In rare cases the following undesirable effects have occurred: blushes, urticaria, nausea, cold chills and other symptoms of anaphylactoid reactions. When the drug is administered too fast palpitations, dyspnoea, heat sensations, transient hypertension and abdominal cramps may occur during or immediately after administration. Within one hour these symptoms disappear. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred. **DOSIMETRY** The effective dose equivalent resulting from an administered activity amount of 200 MBq is 2.6 mSv in adults. **OVERDOSE** The effect of an overdose of iobenguane is due to the release of adrenaline. This effect is of short duration and requires supportive measures aimed at lowering the blood pressure. Maintain a high urine flow to reduce the influence of radiation. **INSTRUCTIONS FOR USE** Swab stopper with suitable disinfectant before removal of dose, then store at 2-8°C, use within one working day. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0140. **UK PRICE** Dependent on activity. For example 370 MBq £689.55. **DATE OF REVISION OF TEXT** 31 March 2009

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Bridatec [N-(3-bromo-2.4.6-trimethylphenylcarbamoyl methyl)-iminodiacetic acid (Mebrofenin), as sodium salt 40.0 mg/vial]

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. This product does not hold a marketing authorisation in the UK but is authorised in Greece, Spain, Portugal, Germany, The Netherlands, Denmark and Finland.

PRESENTATION Kit for radiopharmaceutical preparation, powder for solution for injection reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection (not included in this kit) to prepare technetium-99m mebrofenin injection. **INDICATIONS** Used as a diagnostic agent in hepatobiliary imaging and hepatobiliary function studies. **DOSAGE AND METHOD OF ADMINISTRATION** Intravenously administered to patients fasting for 6 hours prior to examination. The recommended dose in adults is 150 to 300 MBq. The dose in children can be calculated from the recommended adult dose adjusted to body weight. In very young children (up to 1 year), a minimum dose of 20 MBq is necessary in order to obtain images of sufficient quality. Commencement of the scintigraphy should be immediately after injection. Cholocystokinins or a fatty meal may be used to contract the gall bladder. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The hepatobiliary imaging and function studies may not be adequately visualized in parenteral nutrition, prolonged dieting, hepatocellular insufficiency, and hepatitis. After a meal the test should be performed with the patient fasted for six hours. Bridatec contains sodium 0.30 mg/ml; this needs to be taken into considerations for patients on a controlled sodium diet. **INTERACTIONS** Opiate analgesics and barbiturates may enhance activity in the gall bladder. Nicotinic acid may impair uptake and excretion in bile. Cholecystokinin and sincalide stimulate gall bladder emptying and secretion into the duodenum. Atropine and somatostatin may impair gall bladder emptying. Gall bladder visualization may be adversely affected in patients receiving chemotherapy via an indwelling hepatic artery catheter. **PREGNANCY AND LACTATION** In pregnancy, only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for twelve hours and expressed feeds discarded. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Adverse reactions have not been reported. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects (evidence suggests that these will occur with low frequency). **DOSIMETRY** The effective doses (ED) for an adult (70 kg individual) resulting from an administered activity of 300 MBq is typically 7.2 mSv for technetium–labelled iminodiacetic acid derivates, 3.9 mSv for parenchymal liver disease, 5.4 mSv for oclusion of the cystic duct and 2.9 mSv for oclusion of the common bile duct. ED equivalent for a newborn is 0.85 mSv/MBq. **MARKETING AUTHORISATION HOLDER** GE Healthcare S.r.l., Via Galeno 36, 20126 Milan, Italy. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **DATE OF REVISION OF TEXT** 31 August 2011

PRESCRIBING INFORMATION CERETEC™ (Kit for radiopharmaceutical preparation)

Indications and approvals may vary in different countries. Please refer to the local Summary of Product Characteristics [SPC] before prescribing. Further information available on request.

PRESENTATION Single dose vial containing 0.5mg exametazime as sterile freeze-dried powder for reconstitution with Sodium Pertechnetate [^{99m}Tc] injection, Ph.Eur. **INDICATIONS** i) Diagnosis of abnormalities of regional cerebral blood flow (rCBF) using brain scintigraphy. ii) *In vitro* ^{99m}Tc-leucocyte labelling, the labelled leucocytes being re-injected for scintigraphic imaging of their sites of localisation. **DOSAGE AND METHOD OF ADMINISTRATION** i) Brain scintigraphy: 350-500 MBq ^{99m}Tc-exametazime by intravenous administration. ii) *In vivo* localisation of ^{99m}Tc-labelled leucocytes: 200 MBq ^{99m}Tc-labelled leucocytes by intravenous administration following *in vitro* leucocyte labelling. ^{99m}Tc-exametazime and ^{99m}Tc-labelled leucocytes are not recommended for administration to children. **CONTRAINDICATIONS** Hypersensitivity to the active substance or any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including serious signs and symptoms of anaphylaxis should always be considered. Advanced life support facilities should be readily available. Re-injected Ceretec labelled leucocytes only: When preparing technetium-99m-labelled leucocytes it is essential that cells are washed free of sedimentation agents before they are re-injected into the patient as materials used in cell separation may cause hypersensitivity reactions. For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result. According to the time of conditioning injection for the patient, the content of sodium may in some cases be greater than 1 mmol. This should be taken into account in patients on low sodium diet. **PREGNANCY AND LACTATION** No data are available on use of this product in human pregnancy. Not recommended during pregnancy except where judged medically necessary. If administration to a breast-feeding woman is necessary, substitute formula feeding for breast-feeding for at least 12 hours. **UNDESIRABLE EFFECTS** Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus , headache, dizziness, paraesthesia, flushing, nausea, vomiting, asthenic conditions (e.g., malaise, fatigue) (all of unknown frequency). Re-injected Ceretec labelled leucocytes only: Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus, anaphylactoid reaction or anaphylactoid shock (all of unknown frequency). Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 555 MBq is administered these adverse events are expected to occur with a low probability. **DOSIMETRY** The Effective Dose following administration of ^{99m}Tc-exametazime is 4.7 mSv per 500 MBq. The effective dose following administration of ^{99m}Tc-labelled leucocytes is 2.2 mSv per 200 MBq. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Bucks, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **MARKETING AUTHORISATION NUMBER** PL00221/0126. **UK PRICE** 5 vial pack £880.80. **DATE OF REVISION OF TEXT**
16 June 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Chromium (^{51}Cr) EDTA 3.7 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, violet solution for injection containing chromium-51 edetate 3.7 MBq/ml (37 MBq/vial) at the activity reference date. **INDICATIONS** Used as a diagnostic agent for the determination of glomerular filtration rate in the assessment of renal function. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended dose for adults and the elderly is 1.1-6.0 MBq by intravenous injection or continuous infusion. Higher activities up to a maximum of 11 MBq may be appropriate for use in conjunction with external counting techniques. The activity administered to children is calculated by correcting on a weight, body surface area or age basis the activity to adults. For children under about one year of age, the target organ size in relation to the whole body must also be taken into consideration. The maximal activity to be used in children must not exceed 3.7 MBq. Normally a single intravenous administration of 3.7 MBq of chromium-51 edetate is given and venous samples are taken at appropriate intervals (for example, two, three, and four hours after administration) with another at 24 hours if renal failure is suspected. The venous samples are spun and the plasma separated and counted, together with an aliquot of the given dose. In case of continuous intravenous infusion, a priming administration of 1.85 MBq is given intravenously followed by the infusion of a solution containing 37 kBq/ml at a rate of 0.5 ml/minute. After about 40 minutes, the plasma concentration becomes constant. A urine collection lasting about 15 minutes is then started and a venous sample taken at the mid-time. This process is repeated with rapid separation and counting of the plasma radioactivity until constant plasma activity is observed in two successive samples. Alternative methods for determining glomerular filtration rate (GFR) using chromium-51 edetate may be used in certain centres. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. It must not be given to premature babies or neonates. **WARNINGS AND PRECAUTIONS** This medicinal product contains benzyl alcohol. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old. The patient should be asked to drink additional fluids and to void the bladder as often as possible following administration to reduce the radiation dose to the bladder and an accumulation of radioactivity in it. Chromium (^{51}Cr) EDTA injection contains sodium 0.23 mg/ml; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** No interaction studies have been performed. **PREGNANCY AND LACTATION** No data available. Animal reproduction studies have not been performed. In pregnancy, only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for four hours and expressed feeds discarded. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with low frequency). Mild allergic phenomena have been reported infrequently after single or repeated intravenous administrations. **DOSIMETRY** Effective dose equivalent (EDE) for an adult (70 kg) resulting from an administered activity of 1.1-6 MBq is typically 0.0025-0.014 mSv in case of normal kidney function and is 0.0057-0.031 mSv under conditions of abnormal renal function. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0108. **PRICE** 37 MBq £335.00. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION DaTSCAN™ ioflupane (^{123}I) 74 MBq/ml solution for injection

Please refer to full Summary of Product Characteristics (SPC) before prescribing. Further information available on request.

PRESENTATION Single dose vials containing 185 MBq or 370 MBq ioflupane (^{123}I) at reference time. **INDICATIONS** Detecting loss of functional dopaminergic neuron terminals in the striatum. **i)** in adult patients with clinically uncertain Parkinsonian Syndromes in order to help differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's Disease (PD), Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP). DaTSCAN is unable to discriminate between PD, MSA and PSP. **ii)** in adult patients to help differentiate probable dementia with Lewy bodies (DLB) from Alzheimer's disease. DaTSCAN is unable to discriminate between DLB and Parkinson's Disease dementia. **DOSAGE AND METHOD OF ADMINISTRATION** Prior to administration appropriate resuscitation equipment should be available. For use in patients referred by physicians experienced in the management of movement disorders/dementia. Clinical efficiency has been demonstrated across the range of 111-185 MBq; do not use outside this range. Appropriate thyroid blocking treatment must be given prior to injection of DaTSCAN. The safety and efficacy of DaTSCAN in children 0 to 18 years has not been established. No data are available in patients with significant renal or hepatic impairment. DaTSCAN should be used without dilution. Slow intravenous injection (15-20 seconds) via an arm vein is recommended. SPECT imaging should take place 3-6 hours after injection of DaTSCAN. **CONTRAINDICATIONS** Pregnancy and hypersensitivity to the active substance or any of the excipients. **WARNINGS AND PRECAUTIONS** If hypersensitivity reactions occur, the administration of the medicinal product must be discontinued immediately and, if necessary, intravenous treatment initiated. Resuscitative medicinal products and equipment (e.g. endotracheal tube and ventilator) have to be readily available. Radiopharmaceuticals should only be used by qualified personnel with appropriate government authorisation and should be prepared using aseptic and radiological precautions. For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result. DaTSCAN is not recommended in cases of moderate to severe renal or hepatic impairment. Contains 39.5 g/l (5% volume) ethanol, up to 197 mg per dose, harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease or epilepsy. **INTERACTIONS** Consider current medication. Medicines that bind to the dopamine transporter with high affinity may interfere with diagnosis; these include amfetamine, benzatropine, buproprion, cocaine, mazindol, methylphenidate, phentermine and sertraline. Medicines shown during clinical trials not to interfere with DaTSCAN imaging include amantadine, trihexyphenidyl, budipine, levodopa, metoprolol, primidone, propranolol and selegiline. Dopamine agonists and antagonists acting on the postsynaptic dopamine receptors are not expected to interfere with DaTSCAN imaging and can therefore be continued if desired. In animal studies pergolide does not interfere with DaTSCAN imaging. **PREGNANCY AND LACTATION** Contraindicated in pregnancy. Information should be sought about pregnancy from women of child bearing potential. A woman who has missed her period should be assumed to be pregnant. If uncertain, radiation exposure should be the minimum needed for satisfactory imaging. Consider alternative techniques. If administration to a breast feeding woman is necessary, substitute formula feeding for breast feeding for 3 days. **UNDESIRABLE EFFECTS** No serious adverse effects have been reported. Common side effects include headache. Uncommon side effects include vertigo, increased appetite, formication, dizziness, dysgeusia, nausea and dry mouth. Intense pain on injection has been reported uncommonly following administration into small veins. Hypersensitivity occurs with unknown frequency. Exposure to ionising radiation is linked with cancer induction and a potential for hereditary defects. Because of the low radiation dose incurred these adverse events are expected to occur with a low probability. **DOSIMETRY** Effective dose from 185 MBq is 4.35 mSv. **OVERDOSE** Encourage frequent micturition and defecation. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription. **MARKETING AUTHORISATION NUMBERS** EU/1/00/135/001 (2.5ml) and EU/1/00/135/002 (5.0ml). **UK PRICE** 185 MBq £525.00. **DATE OF REVISION OF TEXT** 7 June 2011.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Drytec

Please refer to the full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information is available on request.

PRODUCT NAME Drytec™. **PRESENTATION** Radionuclide generator for the production of Sodium Pertechnetate (^{99m}Tc) Injection Ph.Eur. The mother nuclide is: Sodium molybdate [^{99}Mo] 2.5-100GBq/generator at the activity reference date. The daughter nuclide is: Sodium pertechnetate [^{99m}Tc] – Variable. **INDICATIONS** The eluate from the generator (Sodium Pertechnetate [^{99m}Tc] Injection Ph. Eur.), may be used as a reagent for labelling of carrier compounds supplied as kits or administered directly *in vivo*. When administered intravenously, the sterile sodium pertechnetate [^{99m}Tc] solution is used as a diagnostic aid in the following: (a) **Thyroid scintigraphy:** Direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in thyroid disease. (b) Salivary gland scintigraphy: to assess salivary gland function and duct patency. (c) **Location of ectopic gastric mucosa:** Meckel's diverticulum. (d) **Cerebral scintigraphy:** to identify breaches in the blood-brain barrier caused by tumour, infarction, haemorrhage and oedema, when no other methods are available. When used in conjunction with pre-treatment with a reducing agent to effect technetium-99m-labelling of red blood cells: (e) **Cardiac and vascular scintigraphy**
• angiocardioscintigraphy for: evaluation of ventricular ejection fraction; evaluation of global and regional cardiac wall motion; myocardial phase imaging
• organ perfusion or vascular abnormalities imaging. (f) **Diagnosis and localisation of occult gastrointestinal bleeding.** Following instillation of sterile sodium pertechnetate [^{99m}Tc] solution into the eye. (g) **Lacrimal duct scintigraphy:** to assess patency of tear ducts. **POSOLOGY AND METHOD OF ADMINISTRATION** Sodium pertechnetate [^{99m}Tc] is normally administered intravenously at activities which vary widely according to the clinical information required and the equipment used. Pre-treatment of patients with thyroid blocking agents or reducing agents may be necessary for certain indications see SPC for recommended activities. In very young children (up to 1 year) a minimum dose of 20MBq (10MBq in thyroid scintigraphy) for direct administration or 80MBq for red blood cell labelling is necessary in order to obtain images of sufficient quality. **CONTRA-INDICATIONS** None known. **SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE** Radiopharmaceutical agents should be used only by qualified personnel with the appropriate government authorisations for the use and manipulations of radionuclides. This radiopharmaceutical may be received, used and administered only by authorised personnel and should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. **INTERACTIONS** Drug interactions have been reported in brain scintigraphy where there can be increased uptake of [^{99m}Tc] pertechnetate in the walls of cerebral ventricles as a result of methotrexate-induced ventriculitis. In abdominal imaging, drugs such as atropine, isoprenaline and analgesics can result in a delay in gastric emptying and redistribution of pertechnetate. **PREGNANCY AND LACTATION** ^{99m}Tc (as free pertechnetate) has been shown to cross the placental barrier. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists, it is important that the radiation exposure should be the minimum consistent with achieving the desired clinical information. Only imperative investigations should be carried out during pregnancy. Direct administration of 800MBq sodium pertechnetate [^{99m}Tc] to a patient results in an absorbed dose to the uterus of 6.5mGy. Following pretreatment of patients with a blocking agent, administration of 800MBq sodium pertechnetate [^{99m}Tc] results in an absorbed dose to the uterus of 5.3mGy. Administration of 925MBq ^{99m}Tc-labelled red blood cells results in an absorbed dose to the uterus of 4.3mGy. Doses above 0.5mGy should be regarded as a potential risk to the foetus. For a woman who is breast feeding, consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast feeding and as to whether the most appropriate choice of radiopharmaceutical has been made. Otherwise breast feeding should be interrupted and the expressed feeds discarded. Breast feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1mSv. **UNDESIRABLE EFFECTS** Allergic reactions have been reported following intravenous injection of sodium pertechnetate [^{99m}Tc] and include urticaria, facial oedema, vasodilation, pruritus, cardiac arrythmias and coma. The activity administered must be such that the resulting radiation is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For full details refer to SPC. **OVERDOSE** Increasing the elimination of the radionuclide from the body for example include frequent voiding of urine and promotion of diuresis and faecal excretion. Very little supportive treatment can be undertaken in the event of an overdose of ^{99m}Tc-labelled red blood cells since elimination is dependent on the normal haemolytic process. **DOSIMETRY** (i) With pre-treatment with blocking agent: The effective dose equivalent resulting from an administered activity of 800MBq sodium pertechnetate [^{99m}Tc] is 10.4mSv. Following pretreatment of patients with a blocking agent, administration of 800MBq sodium pertechnetate [^{99m}Tc] results in an effective dose equivalent of 4.24mSv. (ii) The radiation doses absorbed by a patient following intravenous injection of ^{99m}Tc-labelled red blood cells. The effective dose equivalent resulting from an administration of 925MBq ^{99m}Tc-labelled red blood cells is 7.86mSv. (iii) The radiation dose absorbed by the lens of the eye following administration of sodium pertechnetate [^{99}mTc] for lacrimal duct scintigraphy is estimated to be 0.038mGy/MBq. This results in an effective dose equivalent of less than 0.01mSv for an administered activity of 4MBq. **INSTRUCTIONS FOR USE, HANDLING AND DISPOSAL INSTRUCTIONS FOR ELUTION OF THE DRYTEC GENERATOR Safe handling** Consideration should be given to the safe lifting and carrying of the generators. **Elution instructions** Facilities should comply with the appropriate regulations for safe radiological handling. Strict aseptic techniques should be used throughout. Refer to SPC for detailed instructions. **Elution volume and yield of technetium-99m** Minimum elution volume for lead

shielded generators is 5ml and for depleted uranium shielded generators is 10ml. **Disposal of expired generators** Shielding should normally be disposed of as radioactive waste. Generators containing depleted uranium and tungsten shielding must be returned to GE Healthcare Limited after expiry. Full instructions describing how the return of generators to GE Healthcare Limited should be carried out are included with each generator. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA United Kingdom. **CLASSIFICATION OF SUPPLY** Prescription only medicine. **MARKETING AUTHORISATION NUMBER** PL 0221/0106 **UK PRICE** Dependent on activity and reference date. For example MCD44Y 20 GBq £813.00. **DATE OF REVISION** 28 February 2007

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Indium (^{111}In) Chloride 370 MBq/ml radiopharmaceutical precursor, solution

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear colourless solution of Indium-111 chloride, 370 MBq/ml at the activity reference date. **INDICATIONS** A diagnostic agent used for radiolabelling of certain suitably derivatised proteins, monoclonal antibodies and injectable preparations. **DOSAGE AND METHOD OF ADMINISTRATION** The vial contains a sterile, isotonic solution for the *in vitro* radiolabelling of suitable conjugated proteins which are subsequently administered intravenously. The quantity of indium-111 chloride required for radiolabelling and the quantity of indium 111-labelled pharmaceutical that is subsequently administered depend on the pharmaceutical being labelled and its intended use. Information on recommended activity and administration will be provided by the manufacturer of the pharmaceutical to be radiolabelled. The activity to be administered to children may be calculated approximately by correcting on a weight, body surface area or age basis, the activity to adults. For the newborn and children under about one year of age, the target organ size in relation to the whole body must also be taken into consideration. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Further information will be supplied by the manufacturer of the pharmaceutical to be radiolabelled. **WARNINGS AND PRECAUTIONS** The contents of the vial of Indium (^{111}In) chloride solution should not be administered directly to the patient without undergoing the preparative procedure. Further information for the use of indium [^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium [^{111}In]chloride will be supplied by the manufacturer of the pharmaceutical to be radiolabelled. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'. **INTERACTIONS** Information associated with the use of indium [^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium [^{111}In]chloride will be supplied by the manufacturer of the pharmaceutical to be radiolabelled. **PREGNANCY AND LACTATION** There is some evidence from animal experiments of teratogenicity of indium in very high doses compared with the maximal possible concentration of free indium chloride in a labeled pharmaceutical. In pregnancy, only imperative investigations should be carried out when likely benefit far exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. Doses above 0.5 mGy should be regarded as a potential risk for the foetus. In breastfeeding mothers, the administration of radionuclide should be delayed until the mother has ceased breastfeeding, bearing in mind the secretion of activity in breast milk. Breast-feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. The availability of data on the use of indium [^{111}In]-labelled pharmaceuticals, prepared by radiolabelling with indium [^{111}In]chloride, in pregnancy and lactation will be specified by the manufacturer of the pharmaceutical to be radiolabelled. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with low frequency). Other side-effects following the intravenous administration of an indium-111 labelled pharmaceutical prepared by radiolabelling with Indium (^{111}In) Chloride Solution will be dependent on the specific pharmaceutical being used. **DOSIMETRY** The radiation dose received by the various organs following intravenous administration of an indium-111 labelled pharmaceutical preparation will be dependent on the specific pharmaceutical being radiolabelled. Effective dose equivalents resulting from the intravenous administration of indium-111 labelled pharmaceuticals will be of the order of 10^{-1} mSv/MBq. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0110. **PRICE** Dependent on activity. For example 74 MBq £245.17. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Indium (^{111}In) Oxine 37 MBq/ml radiopharmaceutical precursor, solution

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution of Indium-111 Oxine, 37 MBq/ml at the activity reference date. **INDICATIONS** Indium 111 oxine is used as an ingredient for the *in vitro* radiolabelling of separated blood cells which are subsequently administered intravenously. Indium-111 labelled leucocytes or granulocytes are used in investigation of sites of inflammatory processes and abscesses, complementary with other imaging investigations. Indium-111 labelled platelets (thrombocytes) are used in determination of platelet survival and biodistribution, particularly spleen and liver uptake in cases of thrombocytopenia, arterial or vascular thrombosis, aneurysms and sites of inflammation in rejecting transplants. Indium-111 labelled erythrocytes are used in investigation of sites of gastro-intestinal haemorrhage. **DOSAGE AND METHOD OF ADMINISTRATION** The vial contains a sterile, isotonic solution for the *in vitro* radiolabelling of blood cells which are subsequently administered intravenously. The recommended activity for adults and the elderly of indium-111 labelled leucocytes or granulocytes is 7.4-30 MBq. Scintigraphic studies to detect focal accumulations of indium-111 labelled leucocytes can be commenced 3-6 hours after administration, and in inflammatory lesions is more marked on scanning 24 hours post-injection. The recommended activity for adults and the elderly of Indium-111 labelled platelets is 1.85-3.7 MBq for platelet survival studies, 3.7-18.5 MBq for platelet distribution studies. Scintigraphic studies to detect deposition of labelled platelets may usefully be commenced 2-6 hours after administration. The recommended activity for adults and the elderly of Indium-111 labelled erythrocytes is 3.7-18.5 MBq. The activity administered to children is calculated by correcting on a weight, body surface area or age basis the activity to adults. For newborn and children under about one year of age, the target organ size in relation to the whole body must also be taken into consideration. In very young children (up to 1 year), a minimum dose of 10% of adult dose is recommended to obtain images of sufficient quality. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including serious anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. **INTERACTIONS** No interaction studies have been performed. Corticosteroids and antibiotics have been reported to reduce uptake of indium-111 labelled leucocytes. Antibiotics may impair leucocyte migration because of reduced chemotactic stimulus. **PREGNANCY AND LACTATION** No data available. There is some evidence from animal studies of teratogenicity of indium. In pregnancy, only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. Advice on avoidance of pregnancy until the calculated dose to the uterus is below 0.5 mGy should be given to women of childbearing potential. Administration of 30 MBq indium-111 labelled leucocytes results in an absorbed dose to the uterus of 3.6 mGy; and administration of 18.5 MBq indium-111 labelled platelets results in an absorbed dose to the uterus of 1.8 mGy. Doses above 0.5 mGy should be regarded as a potential risk for the foetus. If the administration is considered necessary, breast feeding should be interrupted and the expressed feeds discarded. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Hypersensitivity, anaphylactoid reaction (evidence suggests that these will occur with unknown frequency). **DOSIMETRY.** Effective dose equivalent (EDE) for an adult (70 kg) resulting from an administered activity of 30 MBq indium-111 labelled leucocytes is 10.8 mSv, activity of 18.5 MBq indium-111 labelled platelets is 7.72 mSv and activity of 18.5 MBq indium-111 labelled erythrocytes is 7.4 mSv. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0100. **PRICE** 37 MBq £207.56. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Maasol (Human albumin macroaggregates, 1.75 mg/vial)
Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. This product does not hold a marketing authorisation in the UK but is authorised in Greece, Germany, Belgium, The Netherlands, Denmark, Finland, Sweden, Norway, Switzerland, Poland and Romania.

PRESENTATION Kit for radiopharmaceutical preparation, powder for suspension for injection reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection (not included in this kit) to prepare technetium-99m albumin macroaggregates injection. **INDICATIONS** Used as a diagnostic agent for pulmonary perfusion scintigraphy and venoscintigraphy. **DOSAGE AND METHOD OF ADMINISTRATION** Recommended activities to be administered intravenously to an adult (70 kg) is between 37-185 MBq (1-5 mCi). The number of particles per administered dose must be in a range of 60×10^3 - 700×10^3. The activity in children can be calculated from the recommended adult activity adjusted to body weight or surface area. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of a hypersensitivity reaction, including life threatening fatal anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. The syringe should be gently swirled immediately prior to the injection to homogenise the injective. Blood should never be drawn into the syringe because that induces the formation of small clots. Special care should be exercised when administering to patients with significant right to left cardiac shunt and respiratory failure. Slow intravenous injection should be given and the number of particles reduced by up to 50%. The risk of transmission of infectious agents, virus and other pathogens cannot be eliminated completely, as long as pharmaceuticals made of human blood or plasma are used. Maasol contains 0.30 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. It is strongly recommended that the product name and batch number are stated every time Maasol is given to a patient. **INTERACTIONS** Pharmacologic interactions are caused by chemotherapeutic agents, heparin and bronchodilators. Toxicological interactions are caused by heroin, nitrofurantoin, busulfan, cyclophosphamide, bleomycin, methotrexate, and methysergide. Pharmaceutical interactions are caused by magnesium sulphate. **PREGNANCY AND LACTATION** In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a lactating woman is considered necessary, breast feeding should be interrupted for twelve hours and expressed feeds discarded. Breast feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Hereditary defects and cancer induction (evidence suggests that these will occur with low frequency). Hypersensitivity including very rare life-threatening anaphylaxis, chest pain, rigor and collapse, and local allergic reactions at the injection site (unknown frequency). **DOSIMETRY** The effective dose (ED) equivalent resulting from an administered activity of 185 MBq is typically 2.2 mSv (per 70 Kg individual). **MARKETING AUTHORISATION HOLDER** GE Healthcare S.r.l., Via Galeno 36, 20126 Milan, Italy. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **DATE OF REVISION OF TEXT** 31 August 2011

PRESCRIBING INFORMATION Macrotec (Human albumin macroaggregates, 2.0 mg/vial)
Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. This product does not hold a marketing authorisation in the UK but is authorised in Portugal, Czech Republic, Bulgaria, Slovakia and Spain.

PRESENTATION Kit for radiopharmaceutical preparation, powder for suspension for injection reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection (not included in this kit) to prepare technetium-99m albumin macroaggregates (Macrosalb) injection. **INDICATIONS** Used as a diagnostic agent for pulmonary perfusion scintigraphy and venoscintigraphy. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended activities administered intravenously to an adult (70 kg) varies between 37-185 MBq (1-5 mCi). The number of particles per administered dose must be in a range of 60×10^3 - 700×10^3. The activity in children can be calculated from the recommended adult activity adjusted to body weight or surface area. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients or to any of the components of the labelled radiopharmaceutical. **WARNINGS AND PRECAUTIONS** The syringe should be gently swirled immediately prior to injection to homogenise the injectate. Blood should never be drawn into the syringe because that induces the formation of small clots. Special care should be exercised when administering to patients with significant right to left cardiac shunt and respiratory failure. Slow intravenous injection should be given and the number of particles reduced by up to 50%. **INTERACTIONS** Pharmacologic interactions are caused by chemotherapeutic agents, heparin and bronchodilators. Toxicological interactions are caused by heroin, nitrofurantoin, busulfan, cyclophosphamide, bleomycin, methotrexate, and methysergide. Pharmaceutical interactions are caused by magnesium sulphate. **PREGNANCY AND LACTATION** In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for twelve hours and expressed feeds discarded. Breast feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1 mSv. **UNDESIRABLE EFFECTS** Hereditary defects, cancer induction (evidence suggests that these will occur with low frequency). Hypersensitive-type reactions with chest pain, rigor and collapse. Local allergic reactions have been seen at the injection site. **DOSIMETRY** The effective dose (ED) equivalent resulting from an administered activity of 185 MBq is typically 2.2 mSv (per 70 Kg individual). **MARKETING AUTHORISATION HOLDER** GE Healthcare S.r.l.,Via Galeno 36, 20126 Milan, Italy. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **DATE OF REVISION OF TEXT** 31 August 2011

PRESCRIBING INFORMATION Metastron 37 MBq/ml solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Clear, colourless solution for injection of strontium-89 chloride 37 MBq/ml. **INDICATIONS** Used an adjunct to and as an alternative to external beam radiotherapy for the palliation of pain from bone metastases secondary to prostatic carcinoma at the stage of hormone therapy failure. **DOSAGE AND METHOD OF ADMINISTRATION** The product should be administered without dilution. The recommended intravenous dose for adults and elderly is 150 MBq (4 mCi) per injection. Alternatively in particularly heavy or light framed patients a dose of 2 MBq (55 µCi)/kg 'fat-free' body weight may be used. Repeat administrations should not be performed within 3 months of the previous Metastron injection. Further administrations are not indicated in patients who have not responded to a previous administration. This product is not for administration to children. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Contraindicated in children. Use of the product in patients with evidence of seriously compromised bone marrow, particularly low neutrophil and platelet counts, is not recommended unless the potential benefit of the treatment is considered to outweigh the risk. Metastron should not be used as a primary treatment for cord compression secondary to spinal metastases where more rapid treatment may be necessary. **WARNINGS AND PRECAUTIONS** Special precautions, such as urinary catheterisation, should be taken following administration of Metastron to patients who are significantly incontinent to minimise risks of radioactive contamination. The haematology of patients should be monitored. In considering repeat administration of Metastron the patient's haematological response to his initial dose, his current platelet levels and any other evidence of marrow depletion should all be carefully considered. A cytotoxic agent may be administered to a patient who has previously received Metastron provided that his haematological parameters are stable and within the normal range. An interval of 12 weeks is recommended between two therapies. The expected time of onset of pain relief (10 to 20 days following Metastron administration) should be taken into account in patient management. It is not recommended to be administered to patients with very short life expectancies. Care should be exercised in the pre-treatment assessment of the haematological status of patients who, for the same cause, have previously received extensive bone radiation and/or another injectable bone-seeking isotope. **INTERACTIONS** Calcium therapy should be discontinued at least 2 weeks before Metastron administration. **PREGNANCY AND LACTATION** Not relevant due to indication. **UNDESIRABLE EFFECTS** Exacerbation of pain within the first few days of administration, haematological toxicity including thrombocytopenia and leucopenia. **DOSIMETRY** Effective dose (ED) for strontium-89 is 465 mSv per 150 MBq. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 0221/0127. **PRICE** 148 MBq £1375.00. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION MYOVIEW™ (Kit for radiopharmaceutical preparation)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Lyophilisate containing 230 micrograms tetrofosmin / vial, for reconstitution with Sodium Pertechnetate [^{99m}Tc] injection Ph. Eur. to yield ^{99m}Tc-tetrofosmin injection. **INDICATIONS** i) Myocardial perfusion agent for use as an adjunct in the diagnosis and localisation of myocardial ischaemia and/or infarction. In patients undergoing myocardial perfusion scintigraphy, ECG-gated SPECT can be used for assessment of left ventricular function (left ventricular ejection fraction and wall motion) ii) As an adjunct to the initial assessments in the characterisation of malignancy of suspected breast lesions where other tests are inconclusive. **DOSAGE AND METHOD OF ADMINISTRATION** For diagnosis and localisation of myocardial ischaemia (using planar or SPECT techniques) and assessment of left ventricular function using ECG-gated SPECT, two intravenous injections are administered, one given at peak stress and one given at rest (in either order). When rest and stress injections are given on the same day, the activity administered for the second dose should result in a myocardial count rate at least three times greater than the residual activity of the first dose. The recommended activity for the first dose is 250-400MBq followed by 600-800MBq for the second dose at least 1 hour later. When rest and stress injections are given on different days, the recommended activity for each dose is 400-600MBq. For studies on larger individuals and for studies employing ECG-gated SPECT the use of activities at the higher end of these ranges is warranted. The total activity administered for the procedure whether performed on one or two days should be restricted to 1200MBq. As an adjunct in the diagnosis and localisation of myocardial infarction 250-400MBq is given at rest. Patients should fast overnight or have only a light meal on the morning of the procedure. Planar or SPECT imaging may be acquired between 15 minutes and 4 hours post-injection. For breast imaging an intravenous injection of 500-750MBq preferably in a foot vein or site other than the arm on the side of suspected breast lesions. Not recommended for use in children or adolescents. **CONTRAINDICATIONS** Pregnancy. Hypersensitivity to tetrofosmin or any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. Breast lesions less than 1cm in diameter may not all be detected. Efficacy in the identification of axillary lesions has not been proven. Activity administered must be such that radiation dose is as low as reasonably achievable. **INTERACTIONS** For cardiac use consider current medication when assessing images as drugs which influence myocardial function and/or blood flow (e.g. beta blockers, calcium antagonists, nitrates) can lead to false negative results in diagnosis of coronary artery disease. **PREGNANCY AND LACTATION** Contraindicated in pregnancy. Information should be sought about pregnancy from women of child bearing potential. A woman who has missed a period should be assumed to be pregnant. If administration to a breast-feeding woman is necessary, substitute formula feeding for breast-feeding for at least 12 hours. **UNDESIRABLE EFFECTS** Adverse drug reactions following administration of ^{99m}Tc-tetrofosmin are very rare (<0.01%). The following have been reported: face oedema, hypersensitivity, allergic and anaphylactic reactions, headache, dizziness, metallic taste, disturbances of smell and taste, flushing, hypotension, dyspnoea, vomiting, nausea, burning mouth, urticaria, itching, erythematous rash, feeling of warmth, white blood cell count increase. Some reactions were delayed by several hours following product administration. Isolated cases of serious reactions have been reported, including anaphylactic reaction (less than 1 in 100,000), single case of severe allergic reaction. The major risk is due to radiation which can cause cancer and genetic changes, these effects are expected to occur with a low frequency. **DOSIMETRY** The effective dose (ED) is 8.5mSv when the maximal recommended activity of 1200MBq is administered. **OVERDOSE** Encourage frequent micturition and defecation. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **MARKETING AUTHORISATION NUMBER** PL00221/0142 (UK). **UK PRICE** 5 vial pack £871.22. **DATE OF REVISION OF TEXT** 16 September 2009

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Nanocoll (Human albumin colloidal particles 500 micrograms/vial)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Kit for radiopharmaceutical preparation, powder for solution for injection reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection (not included in this kit) to prepare technetium-99m albumin nanocolloid injection. **INDICATIONS** Used as a diagnostic agent only. Intravenous administration for bone marrow scanning and inflammation scanning in areas other than the abdomen. Subcutaneous administration for lymphatic scanning to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended activities in adults for bone marrow scanning is 185-500 MBq and for inflammation imaging 370-500 MBq (intravenous administration). The recommended activity for lymphoscintigraphy by single or multiple subcantaneous (interstitial) injection ranges from 18.5-110 MBq per injection site. The injected volume should not exceed 0.2-0.3 ml. A maximum volume of 0.5 ml per injection is critical. The dose in children can be calculated from the recommended adult dose adjusted to body weight or surface area. In very young children (up to 1 year) a minimum dose of 20 MBq (bone marrow scanning) is necessary in order to obtain images of sufficient quality. In children, it is possible to dilute the product up to 1:50 with sodium chloride for injection. This agent is not intended for regular or continuous administration. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. During pregnancy, lymphoscintigraphy involving the pelvis is strictly contraindicated. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including serious, life threatening, fatal anaphylactic/anaphylactoid reactions should always be considered. Lymphoscintigraphy is not advised in patients with total lymphatic obstruction. Nanocoll contains 0.30 mg sodium/vial; this needs to be taken into considerations for patients on a controlled sodium diet. **INTERACTIONS** Iodinated contrast media used in lymphoangiography may interfere with lymphatic scanning using technetium-99m albumin nanocolloid. **PREGNANCY AND LACTATION** During pregnancy subcutaneous administration for lymphoscintigraphy is strictly contraindicated because of the accumulation in the pelvic lymph nodes. In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. The absorbed dose to the uterus with intravenous administration of 500 MBq technetium-99m albumin nanocolloïd is 0.9 mGy. Dose to the uterus above 0.5 mGy will be regarded as a potential risk to the foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for thirteen hours and expressed feed is discarded. **UNDESIRABLE EFFECTS** Hypersensitivity (including very rare life threatening anaphylaxis). Hereditary defects and cancer induction (evidence suggests that these will occur with low frequency). **DOSIMETRY** The effective dose (ED) for an adult resulting from intravenous administration of 500 MBq is 2.5 mSv and from subcutaneous administration of 110 MBq is 0.44 mSv (per 70 Kg individual). **MARKETING AUTHORISATION HOLDER** GE Healthcare S.r.l., Via Galeno, 36, 20126 Milan, Italy. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 16991/0001. **PRICE** 5 vial pack £325.00. **DATE OF REVISION OF TEXT** 19 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION RAPISCAN® (regadenoson)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

INDICATION Pharmacological stress agent for radionuclide myocardial perfusion imaging in adult patients. **DOSAGE AND ADMINISTRATION** Each 5 mL vial contains 400 micrograms regadenoson, which is injected over 10 seconds into a peripheral vein followed by 5 mL saline (0.9% sodium chloride) solution flush. The radiopharmaceutical should be administered 10-20 seconds after saline injection. The same catheter may be used for Rapiscan and the radiopharmaceutical. **CONTRA-INDICATIONS** Hypersensitivity to active substance or excipients; patients with second or third degree AV block or sinus node dysfunction who do not have a functioning artificial pacemaker; unstable angina that has not been stabilised with medical therapy; severe hypotension; decompensated heart failure. **PRECAUTIONS** Rapiscan has the potential to cause serious and life-threatening reactions.
Continuous ECG monitoring should be performed and vital signs monitored at frequent intervals until ECG parameters, heart rate and blood pressure have returned to pre-dose levels. Aminophylline may be administered by slow intravenous injection to attenuate severe and/or persistent adverse reactions to Rapiscan. Fatal cardiac arrest, life-threatening ventricular arrhythmias, and myocardial infarction may result from the ischaemia induced by pharmacologic stress agents like regadenoson. Adenosine receptor agonists including regadenoson can depress the sinoatrial (SA) and AV nodes and may cause first, second or third degree AV block, or sinus bradycardia. Adenosine receptor agonists including regadenoson induce arterial vasodilation and hypotension. The risk of serious hypotension may be higher in patients with autonomic dysfunction, hypovolemia, left main coronary artery stenosis, stenotic valvular heart disease, pericarditis or pericardial effusions, or stenotic carotid artery disease with cerebrovascular insufficiency. Adenosine receptor agonists may cause bronchoconstriction and respiratory compromise. For patients with known or suspected bronchoconstrictive disease, chronic obstructive pulmonary disease (COPD) or asthma, appropriate bronchodilator therapy and resuscitative measures should be available prior to Rapiscan administration. Regadenoson stimulates sympathetic output and may increase the risk of ventricular tachyarrhythmias in patients with a long QT syndrome. This medicinal product contains less than 1 mmol sodium (23 mg) per dose. However, the injection of sodium chloride 9 mg/ml (0.9%) solution given after Rapiscan contains 45 mg of sodium. To be taken into consideration by patients on a controlled sodium diet. **UNDESIRABLE EFFECTS** Adverse reactions in most patients were mild, transient (usually resolving within 30 minutes) and required no medical intervention. Rapiscan may cause myocardial ischaemia, hypotension leading to syncope and transient ischaemic attacks, and SA/AV node block requiring intervention. Aminophylline may be used to attenuate severe or persistent adverse reactions. Very common adverse events reported were dyspnoea, headache, flushing, chest pain, electrocardiogram ST changes, gastrointestinal discomfort, and dizziness. Common adverse events reported were paraesthesia, hypoaesthesia, dysgeusia, angina pectoris, atrioventricular block, tachycardia, palpitations, other ECG abnormalities including electrocardiogram QT corrected interval prolonged, hypotension, throat tightness, throat irritation, cough, vomiting, nausea, oral discomfort, back, neck or jaw pain, pain in extremity, musculoskeletal discomfort, hyperhidrosis, malaise, and asthenia. See SPC for details of other undesirable effects. **PRESENTATION AND BASIC NHS PRICE** One carton contains a single vial of Rapiscan (400 micrograms regadenoson in 5 mL solution for injection). Price is £39.50 per vial. **ATC CODE** C01EB21. **LEGAL CLASSIFICATION** POM. **PRODUCT LICENCE HOLDER** Rapidscan Pharma Solutions EU Ltd, Regent's Place, 338 Euston Road, London, NW1 3BT, United Kingdom, is the Marketing Authorization Holder. **MARKETING AUTHORIZATION NUMBER** EU/1/10/643/001. **DATE OF PREPARATION:** March 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported by phone 080 0652 1391, fax 080 0471 5035, or email safety@rapiscan-mpi.com.

PRESCRIBING INFORMATION SeHCAT 370kBq Capsules ([^{75}Se]tauroselcholic acid)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Capsules of [^{75}Se]tauroselcholic acid [370kBq] absorbed onto disodium hydrogen phosphate dihydrate. **INDICATIONS** Used for the investigation of bile acid malabsorption and measurement of bile acid pool loss. It may be used in the assessment of ileal function, in the investigation of inflammatory bowel disease and chronic diarrhoea and in the study of entero-hepatic circulation. **DOSAGE AND METHOD OF ADMINISTRATION** Normal adult dose is one capsule administered orally. A similar dose maybe used in children. A careful assessment of the risk/benefit ratio should be undertaken before use of the product in children due to increased effective dose equivalent. Drinks of water are recommended before, during and after swallowing capsule to ensure passage to the stomach. Patient should be in standing or sitting position. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity should always be considered. Advanced life support facilities should be readily available. Caution advised in administration for SeHCAT to patients with severe hepatic dysfunction or biliary tract obstruction. Radiation dose to liver will be significantly increased in these patients. Exposure to ionising radiation must be justifiable on the basis of likely benefit. The product contains 71.04mg sodium per capsule; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** No interaction studies have been performed and no interactions reported to date. **PREGNANCY AND LACTATION** No data available. Animal reproduction studies have not been carried out. In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques not involving ionizing radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted and breast milk discarded for three to four hours after administration. **UNDESIRABLE EFFECT**S Hypersensitivity (unknown frequency) **DOSIMETRY** Effective dose (ED) for an adult administered one 370KBq capsule of SeHCAT is typically 0.26mSv. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Bucks, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 0221/0105. **PRICE** 370 KBq £195.00. **DATE OF REVISION OF TEXT** 7 February 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Sodium Chromate (^{51}Cr) 37 MBq/ml radiopharmaceutical precursor, solution

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Radiopharmaceutical precursor solution containing sodium [^{51}Cr]chromate, 37 MBq/ml at the activity reference date. **INDICATIONS** Sodium Chromate (^{51}Cr) is used for *in vitro* /*ex vivo* red blood cell labelling and is intended only for diagnostic use. Radiolabelled erythrocytes are used for determination of red cell volume (RCV) in the diagnosis of polycythaemias, anaemias associated with splenomegaly, and pseudoanaemia secondary to an expanded plasma volume. Red cell survival (RCS) studies are performed in patients with haemoglobinopathies, haemolytic anaemias and in whom there is a need to assess transfusion requirements after blood incompatibility reactions. It is also used to establish sites of cell sequestration (liver, spleen) particularly when considering splenectomy in patients with chromic haemolysis or idiopathic thrombocytopenic purpura. Chromium-51 tagged erythrocytes may be used to quantify chronic gastrointestinal blood loss. **DOSAGE AND METHOD OF ADMINISTRATION** Sodium Chromate (^{51}Cr) is intended only for *in vitro* labelling of red blood cells which are subsequently re-injected into the patient. For red cell volume and survival, 10-15 ml of blood is removed by venesection and centrifuged and the red cells incubated with the radioactive solution. To minimise damage to red cells, blood pH should be maintained using appropriate additives. Excess unbound isotope may be removed by washing the cells in isotonic saline or plasma. The cells are then re-suspended in saline before re-injection. Serial blood samples may then be subsequently removed for counting and radiokinetic calculations. Sequestration sites in the body are identified by external counting. The recommended activity for estimation of RCV is 3.7-7.4 kBq/kg body weight i.e. 260-520 kBq/70 kg individual, for estimation of RCS is ≤ 18.5 kBq/kg body weight i.e. 740-1300 kBq/70 kg individual, for RCS and sequestration is ≤ 50 kBq/kg body weight i.e. ≤ 4 MBq/70 kg body weight and for detection of gastrointestinal bleed is 0.74-4 MBq/70 kg individual. The activity in children can be calculated from the recommended adult dose adjusted to body weight or surface area. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The product is not to be administered directly to the patient. The contents of the vial are intended only for the *in vitro* labelling of red blood cells for subsequent intravenous administration. The product contains 3.55 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** No interaction studies have been performed. **PREGNANCY AND LACTATION** Alternative techniques which do not involve ionising radiation should be considered. Any woman who has missed a period should be assumed to be pregnant. Radionuclide procedures carried out on pregnant woman delivering doses of more than 0.5 mGy to the uterus are considered hazardous. The expected absorbed dose to the uterus after administering an activity of 4 MBq sodium [^{51}Cr]chromate has been estimated to be 0.4 mGy although lower activities would normally be utilised. Teratogenic effects are also reported after repeated administration in animal studies. There are no data relating to the excretion of the chromium-51 after cell labelling in breast milk. Where an investigation to a breast-feeding mother is considered mandatory the monitoring of breast milk radioactivity may be indicated. The suckling infant should not receive breastfeed which would lead to overall exposures in excess of 1 mSv effective dose. **UNDESIRABLE EFFECTS** Cancer induction and hereditary defects (evidence suggests that these will occur with low frequency). **DOSIMETRY** The effective dose (ED) resulting from an administered activity of 4 MBq is 0.68 mSv (per 70 kg individual). **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0111. **PRICE** Dependent on activity. For example 37 MBq £210.00. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION STABILISED CERETEC™ (Kit for radiopharmaceutical preparation)

Indications and approvals may vary in different countries. Please refer to the local Summary of Product Characteristics [SPC] before prescribing. Further information available on request.

PRESENTATION Single dose vial containing 0.5mg exametazime as sterile freeze-dried powder for reconstitution with Sodium Pertechnetate [^{99m}Tc] injection, Ph.Eur. **INDICATIONS** Diagnosis of abnormalities of regional cerebral blood flow (rCBF) using brain scintigraphy. **DOSAGE AND METHOD OF ADMINISTRATION** Brain scintigraphy: 350-500MBq ^{99m}Tc-exametazime by intravenous administration. **CONTRAINDICATIONS** Hypersensitivity to the active substance or any of the excipients. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including serious signs and symptoms of anaphylaxis should always be considered. Advanced life support facilities should be readily available. For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result. According to the time of conditioning injection for the patient, the content of sodium may in some cases be greater than 1 mmol. This should be taken into account in patients on low sodium diet. **PREGNANCY AND LACTATION** No data are available on use of this product in human pregnancy. Not recommended during pregnancy except where judged medically necessary. If administration to a breast-feeding woman is necessary, substitute formula feeding for breast-feeding for at least 12 hours. **UNDESIRABLE EFFECTS** Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus, headache, dizziness, paraesthesia, flushing, nausea, vomiting, asthenic conditions (e.g., malaise, fatigue) (all of unknown frequency). Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 555 MBq is administered these adverse events are expected to occur with a low probability. **DOSIMETRY** The Effective Dose following administration of ^{99m}Tc-exametazime is 4.7 mSv per 500 MBq. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Bucks, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **MARKETING AUTHORISATION NUMBER** PL00221/0136. **UK PRICE** 5 vial pack £1103.45. **DATE OF REVISION OF TEXT** 27 June 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION SteriPET™ Fludeoxyglucose (^{18}F) 250MBq/ml. Solution for injection

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION 1ml solution for injection contains 250MBq Fludeoxyglucose (^{18}F) [FDG(^{18}F)] at the date and time of calibration. The activity per vial ranges from 250MBq to 2.5GBq. **INDICATIONS** FDG(^{18}F) is indicated for use with positron emission tomography (PET). ***Oncology*** SteriPET is indicated for imaging in patients undergoing oncologic diagnostic procedures describing function or diseases where enhanced glucose influx of specific organs or tissues is the diagnostic target. **Diagnosis:** Characterisation of solitary pulmonary nodule. Detection of cancer of unknown origin, revealed for example by cervical adenopathy, liver or bones metastases. Characterisation of a pancreatic mass. **Staging:** Head and neck cancers including assistance in guiding biopsy. Primary lung cancer. Locally advanced breast cancer. Oesophageal cancer. Carcinoma of the pancreas. Colorectal cancer particularly in restaging recurrences. Malignant lymphoma. Malignant melanoma, Breslow >1.5mm or lymph node metastasis at first diagnosis. **Monitoring of therapeutic response:** Malignant lymphoma. Head and neck cancers. **Detection in case of reasonable suspicion of recurrences:** Glioma with high grade of malignancy (III or IV). Head and neck cancers. Thyroid cancer (non-medullary): patients with increased thyroglobulin serum levels and negative radioactive iodine whole body scintigraphy. Primary lung cancer. Breast cancer. Carcinoma of the pancreas. Colorectal cancer. Ovarian cancer. Malignant lymphoma. Malignant melanoma. ***Cardiology*** Evaluation of myocardial viability in patients with severe impaired left ventricular function who are candidates for revascularisation when conventional imaging modalities are not contributive. ***Neurology*** Localisation of epileptogenic foci in the presurgical evaluation of partial temporal epilepsy. **DOSAGE AND METHOD OF ADMINISTRATION** The recommended activity for adults is 100 to 400MBq , depending on body weight and camera type, by direct intravenous injection. Few clinical data are available for patients under 18, therefore use in paediatrics has to be carefully weighted. Children and adolescents: administer a fraction of the activity recommended for adults. Scans are usually started 45 to 60 minutes after injection. Provided a sufficient activity remains for adequate counting statistics, FDG(^{18}F) PET can also be performed up to two or three hours after administration, thus reducing background activity. If required, repeated examinations can be carried out at short notice. **CONTRAINDICATIONS** Patients with known hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** **Indication of the examination** For all patients, the radiation exposure must be justifiable by the expected diagnostic information achieved with the lowest possible radiation dose. In patients with reduced kidney function, a very careful indication is required since an increased radiation exposure is possible in these patients. It should be taken into consideration that the effective dose per MBq is higher in children than in adults. **Patient preparation** SteriPET should be given to sufficiently hydrated patients fasting for a minimum of 4 hours (beverages containing glucose must be avoided). Patients should be encouraged to drink sufficient amounts and to empty the bladder prior to and after the PET examination. Oncology and neurology. In order to avoid hyperfixation of the tracer in muscle, it is advisable for patients to avoid all strenuous physical activity prior to the examination and to remain at rest between the injection and examination and during acquisition of images (patients should be comfortably lying down without reading or speaking). A blood glucose test should be performed prior to administration since hyperglycaemia may result in a reduced sensitivity of SteriPET, especially when glycaemia is greater than 8mmol/L. FDG(^{18}F)-PET should be avoided in subjects presenting with uncontrolled diabetes. Cardiology. Since glucose uptake in the myocardium is insulin-dependent, for a myocardial examination a glucose loading of 50g approximately 1 hour prior to the administration of SteriPET is recommended. Alternatively, especially for patients with diabetes mellitus, the blood sugar level can be adjusted by a combined infusion of insulin and glucose (Insulin-Glucose-Clamp) if needed. **Interpretation of the FDG PET images** Infectious and/or inflammatory diseases as well as regenerative processes after surgery can result in a significant uptake of FDG and therefore lead to false positive results. False positive or false negative FDG-PET results cannot be excluded after radiotherapy within the first 2-4 months. If the clinical indication is demanding an earlier diagnosis by FDG-PET, the reason for earlier FDG-PET examination must be reasonably documented. A delay of at least 4-6 weeks after the last administration of chemotherapy is optimal, in particular to avoid false negative results. If the clinical indication is demanding an earlier diagnosis by FDG-PET, the reason for earlier FDG-PET examination must be reasonably documented. In case of chemotherapy regimen with cycles shorter than 4 weeks, the FDG-PET examination should be done just before re-starting a new cycle. In low-grade lymphoma and suspicion of recurrence of ovarian recurrent cancer, only positive predictive values have to be considered because of a limited sensitivity of FDG-PET. FDG(^{18}F) is not effective in detecting brain metastases. When applying a coincidence PET (positron emission tomography) scanner system, sensitivity is reduced in comparison to dedicated PET, resulting in reduced detection of lesions smaller than 1cm. It is recommended that FDG(^{18}F)-PET images are interpreted in relation with tomographic anatomical imaging modalities (e.g. CT, ultrasonography, MRI). Fusion of the functional FDG(^{18}F)-PET images with morphologic images e.g. PET-CT can lead to an increased sensitivity and specificity, and is recommended in pancreas, head and neck tumours, lymphoma, melanoma, lung cancers and recurrent colorectal cancers. **General warnings** It is recommended to avoid any close contact between the patient and young children during the initial 12 hours following the injection. Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings and receipt, storage, use, transfer and disposal are subject to the regulations and appropriate licences of the competent

authorities. Radiopharmaceuticals should be prepared by the user in a manner that satisfies both radiation safety and pharmaceutical quality requirements. SteriPET should be stored and handled in adequate shielding, so as to protect patients and hospital staff as much as possible. In particular by using an appropriate shielding when performing withdrawals from the vial and injections. **INTERACTIONS** All medicinal products that modify blood glucose levels can affect the sensitivity of the examination (e.g. corticosteroids, valproate, carbamazepine, phenytoin, phenobarbital and catecholamines). Under administration of colony-stimulating factors (CSFs), there is an increased uptake of FDG(^{18}F) in the bone marrow and the spleen for several days. This must be taken into account for the interpretation of PET imaging. Separating CSF therapy from PET imaging by an interval of at least 5 days may diminish this interference. The administration of glucose and insulin influences the influx of FDG(^{18}F) into the cells. In the case of high blood glucose levels as well as low plasma insulin levels, the influx of FDG(^{18}F) into organs and tumours is reduced. **PREGNANCY AND LACTATION** There is no clinical experience with the use of FDG(^{18}F) in pregnant women. When it is necessary to administer radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists, it is important that radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques that do not involve ionising radiation have to be considered. Radionuclide procedures carried out on pregnant women involve radiation doses to the foetus. Administration of SteriPET at activity of 400MBq results in an absorbed dose to the uterus of 8.4mGy. In this dose range, lethal effects and the induction of malformations, growth retardations and functional disorders are not to be expected; however, the risk of the induction of cancer and hereditary defects may be increased. SteriPET should not be administered during pregnancy unless clearly necessary or when the benefit of the mother outweighs the risk of the foetus. FDG(^{18}F) is excreted into breast milk. Before administering FDG(^{18}F) to a mother who is breast feeding, consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast feeding. If administration during lactation is unavoidable, breast feeding has to be interrupted for at least 12 hours and the expressed milk has to be discarded. When appropriate, milk may be drawn off prior to administration of SteriPET. Moreover, for radioprotection reasons, it is recommended to avoid close contact between the mother and the infant during the initial 12 hours following injection. **UNDESIRABLE EFFECTS** Undesirable effects after the administration FDG(^{18}F) have not been observed to date. Since the administered substance quantity is very low, the major risk is caused by the radiation. Exposure to ionising radiation can lead to cancer or development of hereditary defects. **DOSIMETRY** ED resulting from the administration of an activity of 400MBq is about 7.6mSv (for an individual weighing 70kg). **OVERDOSE** Increase as much as possible the elimination of the radionuclide, by forced diuresis and frequent micturition. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **MARKETING AUTHORISATION NUMBER** PL 00221/0171. **UK PRICE** Price available on request. **DATE OF REVISION OF TEXT** 21 December 2006

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION THERACAP^{131} 37 MBq-5.55 GBq Capsules (sodium [^{131}I] iodide)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

PRESENTATION Single, yellow, hard gelatin capsules containing sodium [^{131}I]iodide in the following dosage range; 37 - 740 MBq in 37 MBq steps, 50 –1000 MBq in 50 MBq steps, 0.925 - 5.55 GBq in 185 MBq steps and 1000 – 5500 MBq in 100 MBq steps at the activity reference date. **INDICATIONS** Used as a therapeutic agent in the treatment of Grave's disease, toxic multinodular goitre or autonomous nodules and treatment of papillary and follicular thyroid carcinoma including metastatic disease. It is often combined with surgical intervention and with antithyroid medications. **DOSAGE AND METHOD OF ADMINISTRATION** The activity administered for the treatment of hyperthyroidism is usually in the range of 200-800 MBq but repeated treatment may be necessary. The dose required depends on the diagnosis, the size of the gland, thyroid uptake and iodine clearance. Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism. For thyroid ablation and treatment of metastases, administered activities following total or sub total thyroidectomy to ablate remaining thyroid tissue are in the range of 1850-3700 MBq. In subsequent treatment for metastases, administered dose is in the range 3700-11100 MBq The dose in children and adolescents can be calculated from the recommended adult dose adjusted to body weight and surface area. The capsules should be swallowed whole. In patients with suspected gastrointestinal disease the capsules should be taken with sufficient fluid to ensure clear passage into the stomach and upper small intestine. Concomitant use of H_2 antagonists or proton pump inhibitors is advised. After high doses used e.g. for the treatment of thyroid carcinoma, patients should be encouraged to increase oral fluids to have frequent bladder emptying to reduce bladder radiation. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Pregnancy and for diagnostic purposes in children under 10 years. Thyroid scanning except in the follow-up of malignant disease or when iodine-123 or technetium-99m is not available. Patients with dysphagia, oesophageal stricture, active gastritis, gastric erosions and peptic ulcer. Patients with suspected reduced gastrointestinal motility. **WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including anaphylactic and anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. The therapeutic administration of sodium [^{131}I]iodide in patients with significant renal impairment requires special attention. Sperm banking should be considered for young men who have extensive disease and therefore may need high radioiodine therapeutic doses. Contraception for 6 months (for patients with benign thyroid conditions) or 12 months (for patients with thyroid cancer) is recommended for both sexes after therapeutic administration. The product contains 140 mg sodium/capsule; this needs to be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** A full drug history should be taken and relevant medication should be withheld prior to administration, including the following: antithyroid agents, perchlorate, salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental, phenylbutazone products, iodine expectorants and vitamins, thyroid hormone preparations, amiodarone, benzodiazepines, lithium, iodine preparations for topical use and iodine contrast media. **PREGNANCY AND LACTATION** Use is contraindicated during pregnancy. The absorbed dose to the uterus is in the range 11-511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. Breast feeding should be discontinued after administration. It is recommended to avoid close contact between mother and child for at least one week after therapeutic dose. **UNDESIRABLE EFFECTS** Bone marrow depression, Sicca syndrome, endocrine ophthalmopathy, acquired dacryostenosis, nausea, vomiting, hypothyroidism, aggravated hyperthyroidism, Graves' disease, hyperparathyroidism, sialoadenitis, gastric cancer, leukaemia, bladder and breast cancer, hypersensitivity, radiation thyroiditis, impairment of fertility in men and woman and congenital thyroid disorders. **DOSIMETRY** The effective dose equivalent in an adult when administered 5.55 GBq with 0% thyroid uptake is 399.6 mSv, with 15% thyroid uptake is 36,630 mSv, with 35% thyroid uptake is 83,250 mSv and with 55% thyroid uptake is 133,200 mSv. **MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **UK MARKETING AUTHORISATION NUMBER** PL 00221/0102. **PRICE** Dependent on activity. For example 3.7 GBq £246.62. **DATE OF REVISION OF TEXT** 31 August 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to GE Healthcare.

PRESCRIBING INFORMATION Venticoll (Human albumin colloidal particles 500 micrograms/vial)

Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request. This product does not hold a marketing authorisation in the UK but is authorised in Germany, Belgium, Denmark, Finland, Norway and Hungary.

PRESENTATION Kit for radiopharmaceutical preparation, powder for nebuliser solution reconstituted with Sodium Pertechnetate (^{99m}Tc) Injection (not included in this kit) to prepare technetium-99m albumin nanocolloid injection. **INDICATIONS** Used as a diagnostic agent only. Administered as an aerosol for diagnosis of pulmonary embolism, in combination with perfusion studies and semi quantitative assessment of pulmonary ventilation. **DOSAGE AND METHOD OF ADMINISTRATION** Depending on the type of nebuliser, an amount of volume and activity of the radiopharmaceutical should be introduced in order to obtain about 100 MBq deposed in the lungs. Ventilation scanning is done immediately after nebulising. Perfusion scanning may be performed immediately after the acquisition of satisfactory ventilation images. The activity for children can be calculated from the recommended range of adult activity adjusted according to body weight or surface area. In children, it is possible to dilute the product up to 1:50 with sodium chloride for injection. This agent is not intended for regular or continuous administration. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS** The risk of transmission of infectious agents, virus and other pathogens cannot be eliminated completely, as long as pharmaceuticals made of human blood or plasma are used. Venticoll contains 0.24 mg/ml sodium; this needs to be taken into consideration for patients on a controlled sodium diet. It is strongly recommended that the product name and batch number are stated every time Venticoll is given to a patient. **INTERACTIONS** No interaction studies have been performed and no interactions have been reported to date. **PREGNANCY AND LACTATION** In pregnancy only imperative investigations should be carried out when likely benefit exceeds the risk to mother and foetus. Any woman who has missed a period should be assumed to be pregnant. Alternative techniques which do not involve ionising radiation should be considered. If administration to a breast feeding woman is considered necessary, breast feeding should be interrupted for thirteen hours and expressed feeds discarded. **UNDESIRABLE EFFECTS** Hereditary defects and cancer induction (evidence suggests that these will occur with low frequency). No cases of anaphylaxis have been reported by patients after aerosol administration. However, after intravenous and subcutaneous administration, hypersensitivity reactions have occurred occasionally. **DOSIMETRY** The effective dose (ED) equivalent for an adult resulting of an administered activity of 100 MBq is 0.5 mSv (per 70 Kg individual). **MARKETING AUTHORISATION HOLDER** GE Healthcare S.r.l., Via Galeno 36, 20126 Milan, Italy. **CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM). **DATE OF REVISION OF TEXT** 31 August 2011

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