1000 mg / 10 ml

℞ Methotrexate
Injection IP 1000mg/10ml

Plastomet

प्लास्टोमेट

For I.M. / I.V. Use

Composition :

Each ml contains :

Methotrexate IP ..... 100 mg

Water for Injection IP ..... q.s.

Dosage and Administration :

See package insert for complete prescribing information

Manufactured in India by :

KLAB

Khandelwal Laboratories Pvt. Ltd.

B-1, Wagle Industrial Estate, Thane 400 604.

Regd. Office : 385, J. Lad Path, Mumbai - 400 [illegible]

Plastomet

M. L. No. : KD-349

B. No. : IMTE10601
बैच क्र.

Mfg. Date : JUN-2021
उत्पादन की तिथि

Expiry Date : MAY-2023
समाप्ति की तिथि

Maximum Retail Price ₹ : 1875.00
(inclusive of all taxes)
अधिकतम खुदरा मूल्य ₹
(सभी करों सहित)

1000 mg / 10 ml

℞ Methotrexate
Injection IP 1000mg/10ml

Plastomet

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Composition :
Each ml of Plastomet-50 contains :
Methotrexate IP .....25 mg
Water for Injection IP .....q.s.

Composition :
Each ml of Plastomet contains :
Methotrexate IP .....100 mg
Water for Injection IP .....q.s.

WARNING:
METHOTREXATE MUST BE USED ONLY BY PHYSICIANS EXPERIENCED IN ANTI-METABOLITE CHEMOTHERAPY.
BECAUSE OF THE POSSIBILITY OF FATAL OR SEVERE TOXIC REACTIONS THE PATIENT SHOULD BE FULLY INFORMED BY THE PHYSICIAN OF THE RISK INVOLVED AND SHOULD BE UNDER HIS CONSTANT SUPERVISION.
DEATHS HAVE BEEN REPORTED WITH THE USE OF METHOTREXATE
IN THE TREATMENT OF PSORIASIS, METHOTREXATE SHOULD BE RESTRICTED TO SEVERE, RECALCITRANT, DISABLING, PSORIASIS WHICH IS NOT ADEQUATELY RESPONSIVE TO OTHER FORMS OF THERAPY BUT ONLY WHEN THE DIAGNOSIS HAS BEEN ESTABLISHED, AS BY BIOPSY AND/OR AFTER DERMATOLOGIC CONSULTATION.

1. Methotrexate may produce marked depression of bone marrow, anemia, leukopenia, thromabocytopenia and bleeding.
2. Methotrexate may be hepatotoxic, particularly at high dose or with prolonged therapy. Liver atrophy, necrosis, cirrhosis, fatty changes, and periportal fibrosis have been reported. Since changes may occur without previous signs of gastrointestinal or hematologic toxicity, it is imperative that hepatic function be determined prior to initiation of treatment and monitored regularly throughout therapy. Special caution is indicated in the presence of pre-existing liver damage or impaired hepatic function. Concomitant use of other drugs with hepatotoxic potential (including alcohol) should be avoided.
3. Malignant lymphomas, which may regress following withdrawal of methotrexate, may occur in patients receiving low-dose methotrexate and, thus, may not require cytotoxic treatment. Discontinue methotrexate first and, if the lymphoma does not regress, appropriate treatment should be instituted.
4. Potentially fatal opportunistic infections, especially Pneumocystis carinii pneumonia, may occur with methotrexate therapy.
5. Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.
6. Unexpectedly severe (sometimes fatal) marrow suppression, aplastic anaemia and gastrointestinal toxicity have been reported with concomitant administration of methotrexate (usually in high doses) with nonsteroidal anti-inflammatory drugs (NSAIDs)
7. Methotrexate has caused fetal death and/or congenital anomalies, therefore, it is not recommended in women of childbearing potential unless there is appropriate medical evidence that the benefits can be expected to outweight the considered risks. Pregnancy should be avoided if either partner is receiving methotrexate, during and for a minimum of 3 months after therapy has ceased, although the optimal time interval between the cessation of methotrexate treatment of either partner, and pregnancy, has not been clearly established.
8. Women should be advised not to breastfeed while being treated with methotrexate
9. Impaired rental function is usually a contraindication.
10. Diarrhoea and ulcerative stomatitis are frequent toxic effects and require interruption of therapy; otherwise hemorrhagic enteritis and death from intestinal perforation may occur.
11. Pulmonary toxicity including pneumonitis and pulmonary fibrosis, which can progress rapidly and is potentially fatal, has been associated with methotrexate therapy. It may occur acutely at any time during therapy and has been reported at low doses. Methotrexate should be discontinued and careful clinical evaluation be performed in patients developing symptoms of pulmonary toxicity (e.g. dry, nonproductive cough, dyspnoea). Pulmonary lesions can occur at all dosages. Infection (including pneumonia) needs to be excluded in patients presenting with symptoms of pulmonary toxicity. Management of Methotrexate induced pulmonary toxicity is mainly supportive. Methotrexate induced pulmonary toxicity may not be fully reversible. Patients should be closely monitored for pulmonary symptoms.

METHOTREXATE HAS BEEN ADMINISTERED IN VERY HIGH DOSAGE FOLLOWED BY LEUCOVORIN RESCUE IN EXPERIMENTAL TREATMENT OF CERTAIN NEOPLASTIC DISEASES. THIS PROCEDURE IS INVESTIGATIONAL AND HAZARDOUS.

DESCRIPTION:
Plastomet Injection is an antimetabolite used in the treatment of certain neoplastic diseases.

ACTION:
Plastomet Injection inhibits the hydrogentation of folic acid and prevents its participation in the synthesis of purines and nucleic acid. It also inhibits anti-body synthesis.

Actively proliferating tissues such as malignant cells, bone marrow, fetal cells, dermal epithelium, buccal and intestinal mucosa and cells of the urinary bladder are in general more sensitive to this effect of Methotrexate. Cellular proliferation in malignant tissue is greater than in most normal tissue and thus Methotrexate may impair malignant growth without irreversible damage to normal tissues.

After parenteral injection, peak serum levels of Methotrexate are seen in about 30 minutes to one hour. Approximately one-half the absorbed Methotrexate is reversibly bound to serum protein, but exchange with body fluids easily and diffuses into the body tissue cells.

INDICATIONS:
Anti-neoplastic Chemotherapy.
Plastomet Injection is indicated for the treatment of gestational chorio-carcinoma, and in patients with chorioadenoma destruens and hydatidiform mole.

Plastomet Injection is indicated for the palliation of acute lymphocytic leukemia. It is also indicated in the treatment and prophylaxis of meningeal leukemia. Greatest effect has been observed in palliation of acute lymphoblastic (stem cell) leukemias in children. In combination with other anticancer drugs or suitable agents Methotrexate may be used for induction of remission, commonly used, in the maintenance of induced remissions.

Plastomet Injection may be used alone or in combination with other anticancer agents in the management of breast cancer, epidermoid cancers of the head and neck, and lung cancer, particularly squamous cell and small cell types.

For the use of a Cancer Specialist or a Hospital or Laboratory

Methotrexate Injection IP 50mg/2ml, 500mg/5ml, 1000mg/10ml

Plastomet

प्लास्टोमेट

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Plastomet Injection may be used alone or in combination with other anticancer agents in the management of breast cancer, epidermoid cancers of the head and neck, and lung cancer, particularly squamous cell and small cell types.

Plastomet Injection is also effective in the treatment of advanced stages (III and IV. Peters Staging System) of lymphosarcoma, particularly in those cases in children; and in advanced cases of mycosis fungoides.

PRECAUTIONS:

METHOTREXATE has high potential toxicity, usually dose related Hematopoietic suppression being a common effect of Methotrexate hematologic studies are essential to its use in Chemotherapy. Profound drop in blood cell count indicates stopping of the drug and appropriate therapy. Methotrexate is excreted principally by the kidney. Its use in the presence of impaired renal function may result in accumulation of toxic amounts or even additional renal damage. The patient's renal status should be determined prior to and during Methotrexate therapy and proper caution exercised should significant renal imprairment be disclosed. Drug dosage should be reduced or discontinued until renal function is improved or restored.

Methotrexate is bound in part to serum albumin after absorption and toxicity may be increased because of displacement by certain drugs such as salicylates, sulfonamides, diphenylhydantoin, phenylbutazone, and some antibacterials as tetracycline, chloramphenicol and para-aminobenzoic acid. These drugs especially salicylates, phenylbutazone, and sulfonamides, whether antibacterials, hypoglycemic or diuretic, should not be given concurrently until the significance of these findings is established.

Vitamin preparations containing folic acid or its derivatives may alter responses to Methotrexate.

Methotrexate should be used with extreme caution in the presence of infection, peptic ulcer, ulcerative colitis, debility, and in extreme youth and old age.

ADVERSE REACTIONS:

The most common adverse reactions include ulcerative stomatitis, leukopenia, nausea and abdominal distress. Others reported are melaise, undue fatigue, chills and fever, dizziness and decreased resistance to infection. In general, the incidence and severity of side effects are considered to be dose-related.

Adverse reactions as reported for the various systems are as follows:

Skin: erythematous rashes, pruritus, urticaria, photosensitivity, depigmentation, alopecia, ecchymosis, telangiectasia, acne, furunculous.

Blood: Bone marrow depression, leukopenia, thrombocytopenia, anemia, hypogammaglobulinemia, hemorrhage from various sites, septicemia.

Alimentary System: Gingivitis, pharyngitis, stomatitis, anorexia, vomiting, Diarrhoea hematemesis, melena, gastrointestinal ulceration and bleeding, enteritis, hepatic toxicity resulting in acute liver atrophy, necrosis, fatty metamorphosis, periportal fibrosis, or hepatic cirrhosis.

Urogenital System: Renal failure, azotemia, cystitis, hematuria; defective oogenesis or spermatogenesis, transient oligospermia, menstrual dysfunction; infertility, abortion, fetal defects, severe nephropathy.

Pulmonary System: Interstitial Pneumonitis Deaths have been reported and chronic interstitial obstructure pulmonary disease has ocassionally occuured.

Central Nervous System: Headaches, drowsiness, blurred vision, Aphasia, hemiparesis, paresis and convulsion have also occured following administration of Methotrexate

DOSAGE AND ADMINISTRATION:

For choriocarcinoma the usual dose is 15 to 30 mg daily for 5 days. Such courses are usually repeated for 3 to 5 times as required, with rest periods of one or more weeks interpost between courses.

In the palliation of inoperable solid tumours 25 mg to 30 mg weekly by Injection is recommended.

Remissions in acute lymphoblastic leukemia has been reduced with doses of 20 to 40 mg per metre body surface given twice weekly by intravenous or intramuscular injections. The dose for maintenance therapy is 15 to 30 mg/m^{2}once or twice a week.

Methotrexate alone or in combination with steroids was used initially for induction of remissions of lymphoblastic leukemia. More recently corticosteroid therapy in combination with other antileukemia drugs or in cyclic combination with Methotrexate included appear to produce rapid and effective reminssian. When used in induction, Methotrexate in doses of 3.3 mg/m in Combination with prednisone 60 mg/m^2, given daily, produced remission in 50% patients treated, usually within a period of 4 to 6 weeks. Methotrexate alone or in combination with other agents appears to be the drug of choice for securing maintenance of drug-inducted remissions. When remission is achieved and supportive care has produced general clinical improvement, maintenance therapy is initiated, as follows: Methotrexate is administered 2 times weekly either by mouth or intramuscularly in doses of 30 mg/m^2.

It has also been given in doses of 2.5 mg/kg intravenously every 14 days. If and when relapse does occur, reinduction of remission can again usually be obtained by repeating the initial induction regimen. Various experts have recently introduced a variety of dosage schedules for both induction and maintenance of remission with various combination of alkylating and antifolic agents. Multiple drug therapy with several agents, including Methotrexate given concomitantly is gaining increasing support in both acute and chronic forms of leukemia. The physician should familiarize himself with the new advances in antileukemic therapy.

Lymphomas: In Burkitt's Tumour, Stages I-II, Methotrexate has produced prolonged remission in some cases. Recommended dosage is 10 to 25 mg per day for 4 to 8 days. In stage III, Methotrexate is commonly given concomitantly with other antitumour agents. Treatment in stages usually consists of several courses of the durg interposed with 7 to 10 days rest periods. Lymphosarcomas in stage III may respond to combined drug therapy with Methotrexate given in doses of 0.625 mg. to 2.5 mg/kg. daily. Hodgkin's Disease responds poorly to Methotrexate and to most types of Chemotherapy.

ANTIDOTE FOR OVER DOSAGE:

Leucovorin is a potent agent for neutralizing immediate toxic effects of Methotrexate on the hematopoietic system where large doses or over doses are given. Calcium Leucovorin may be administered by intravenous infusion in doses upto 75 mg within 12 hours followed by 12 mg i.m. every six hours for four doses. Where average dose of Biotrexate appears to have adverse effect, 6-12 mg of Calcium Leucovorin may be given i.m. every six hours for four doses. In general, where over dosage is suspected, the dose of Leucovorin should be equal to or higher than the offending dose of Methotrexate.

CAUTION:

Because of potential to cause severe toxicity, Plastomet Injection must be used by Oncologists or by Physicians experienced in antimetabolite chemotherapy.