L-152mm x W-15mm x H-74mm

10 Ampoules of 1 ml

PHYTOMENADIONE INJECTION IP

Merit Organics Ltd.

For I.M. /I.V. Use Only

PHYTOMENADIONE INJECTION IP

PHYTOMENADIONE INJECTION IP

PHYTOMENADIONE INJECTION IP

Composition:
Each ml contains:

Phytomenadione	IP	10 mg
Water for injection	IP	q.s.

Do not use if you observe drops of oil or separation

Dosage: As directed by the physician.

Storage: Store at a temperature below 30°C,
Protect from light.

Keep medicine out of reach of children.

Do not freeze.

Mfg. Lic. No. : **G/25/1267**
Batch No. :
घान संख्या
Mfg. Date :
उत्पादन तिथि
Exp. Date :
अवसान तिथि
M.R.P. Rs. :
अधिकतम खुदरा मूल्य
Incl. of all Taxes
सभी कर सहित

NVZ

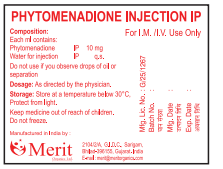
Manufactured by :

Merit Organics Ltd.

2104/2/A, G.I.D.C., Sarigam,
Bhilad - 396 155, Gujarat. India
E-mail : merit@meritorganics.com

PHYTOMENADIONE INJECTION IP

Ampoule
27mm x 21mm



Zoom View

PHYTOMENADIONE INJECTION IP

Composition:

For I.M. /I.V. Use Only

Each ml contains:

Phytomenadione	IP	10 mg
Water for injection	IP	q.s.

Do not use if you observe drops of oil or separation

Dosage: As directed by the physician.

Storage: Store at a temperature below 30°C, Protect from light.

Keep medicine out of reach of children.
Do not freeze.

Mfg. Lic. No. : G/25/1267
Batch No. : .. घान संख्या
Mfg. Date : .. उत्पादन तिथि
Exp. Date : .. अवसान तिथि

Manufactured in India by :

Merit Organics Ltd.

2104/2/A, G.I.D.C., Sarigam,
Bhilad-396155, Gujarat. India
E-mail : merit@meritorganics.com

Front Side

100MM

165 MM

PHYTOMENADIONE INJECTION IP

Composition:
Each ml contains:
Phytomenadione IP 10 mg
Water for injection IP q.s.

INDICATION:
Vitamin K1 Injection (Phytomenadione Injectable , BP) is indicated in the following coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity. Vitamin K1 Injection is indicated in:

- anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives;
- prophylaxis and therapy of hemorrhagic disease of the newborn; hypoprothrombinemia due to antibacterial therapy;
- hypoprothrombinemia secondary to factors limiting absorption or synthesis of vitamin K, e.g., obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas, and regional enteritis;
- other drug-induced hypoprothrombinemia where it is definitely shown that the result is due to interference with vitamin K metabolism, e.g., salicylates.

Contraindications
Hypersensitivity to any component of this medication.

Warnings

- Benzyl alcohol as a preservative in Bacteriostatic Sodium Chloride Injection has been associated with toxicity in newborns. Data are unavailable on the toxicity of other preservatives in this age group. There is no evidence to suggest that the small amount of benzyl alcohol contained in Vitamin K1 Injection (Phytomenadione Injectable, BP), when used as recommended, is associated with toxicity.
- An immediate coagulant effect should not be expected after administration of Phytomenadione. It takes a minimum of 1 to 2 hours for measurable improvement in the prothrombin time. Whole blood or component therapy may also be necessary if bleeding is severe. Phytomenadione will not counteract the anticoagulant action of heparin. When vitamin K1 is used to correct excessive anticoagulant-induced hypoprothrombinemia, anticoagulant therapy still being indicated, the patient is again faced with the clotting hazards existing prior to starting the anticoagulant therapy. Phytomenadione is not a clotting agent, but overzealous therapy with vitamin K1 may restore conditions which originally permitted thromboembolic phenomena. Dosage should be kept as low as possible, and prothrombin time should be checked regularly as clinical conditions indicate.
- Repeated large doses of vitamin K are not warranted in liver disease if the response to initial use of the vitamin is unsatisfactory. Failure to respond to vitamin K may indicate that the condition being treated is inherently unresponsive to vitamin K. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants. WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they required large amounts of calcium and phosphate solutions, which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Precautions
Drug Interactions
Temporary resistance to prothrombin-depressing anticoagulants may result, especially when larger doses of Phytomenadione are used. If relatively large doses have been employed, it may be necessary when reinstituting anticoagulant therapy to use somewhat larger doses of the prothrombin- depressing anticoagulant, or to use one which acts on a different principle, such as heparin sodium.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies of carcinogenicity, mutagenesis or impairment of fertility have not been conducted with Vitamin K1 Injection (Phytomenadione Injectable Emulsion, USP).

Pregnancy
Pregnancy Category C: Animal reproduction studies have not been conducted with Vitamin K1 Injection. It is also not known whether Vitamin K1 Injection can cause fetal harm when

Back Side

100MM

165 MM

administered to a pregnant woman or can affect reproduction capacity. Vitamin K1 Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Vitamin K1 Injection is administered to a nursing woman.

Pediatric Use
Hemolysis, jaundice, and hyperbilirubinemia in neonates, particularly those that are premature, may be related to the dose of Vitamin K1 Injection. Therefore, the recommended dose should not be exceeded.

Adverse Reactions
Deaths have occurred after intravenous and intramuscular administration. Transient "flushing sensations" and "peculiar" sensations of taste have been observed, as well as rare instances of dizziness, rapid and weak pulse, profuse sweating, brief hypotension, dyspnea, and cyanosis. Pain, swelling, and tenderness at the injection site may occur. The possibility of allergic sensitivity including an anaphylactoid reaction, should be kept in mind. Infrequently, usually after repeated injection, erythematous, indurated, pruritic plaques have occurred; rarely, these have progressed to scleroderma-like lesions that have persisted for long periods. In other cases, these lesions have resembled erythema perstans. Hyperbilirubinemia has been observed in the newborn following administration of Phytomenadione. This has occurred rarely and primarily with doses above those recommended.

Overdosage
The intravenous LD50 of Vitamin K1 Injection (Phytomenadione Injectable , BP) in the mouse is 41.5 and 52 mL/kg for the 0.2% and 1% concentrations, respectively.

Dosage and Administration

Vitamin K1 Injection (Phytonadione Injectable Emulsion, USP) Summary of Dosage Guidelines (See circular text for details)

Newborns	**Dosage**
Hemorrhagic Disease of the Newborn Prophylaxis Treatment	0.5 to 1 mg IM within 1 hour of birth 1 mg SC or IM (Higher doses may be necessary if the mother has been receiving oral anticoagulants)
Adults	**Initial Dose**
Anticoagulant-Induced Prothrombin Deficiency (caused by coumarin or indanedione derivatives)	2.5 mg to 10 mg or up to 25 mg (rarely 50 mg)
Hypothrombinemia Due to other causes (Antibiotics; Salicylates or other drugs; Factors limiting absorption or synthesis.	2.5 mg to 25 mg or more (rarely up to 50 mg)

How Supplied
Vitamin K1 Injection (Phytomenadione Injectable Emulsion, USP) is supplied in a package of 10 Amber ampoules in a Plastic Tray with Packaging Insert.

Storage: Store at a temperature below 30°C,
Protect from light.

Keep medicine out of reach of children.

Do not freeze.

Manufactured by :
Merit Organics Ltd.
2104/2/A, G.I.D.C., Sarigam,
Bhilad - 396 155, Gujarat. India
E-mail : merit@meritorganics.com