- Complies with Needlestick Safety and Prevention Act
- Preservative free formulation (does not contain benzyl alcohol or phenol)
- Eliminates handling of ampules and filter needles

PHYTONADIONE
Injection, USP
Safety Prefilled Syringe (Saf-T-Jet™)

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Phytonadione Injection, USP	Saf-T-Jet™	1 mg/0.5 mL	10	76329-1240-1

	WHOLESALER ITEM NUMBERS			
NDC#	AMERISOURCE BERGEN	CARDINAL	MCKESSON	MORRIS & DICKSON
76329-1240-1	10129722	4933784	2046712	768556

TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136

INTERNATIONAL MEDICATION SYSTEMS, LTD.
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Please see reverse for important safety information for Phytonadione Injection, USP.

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PHYTONADIONE
Injection, USP

Rx Only

INDICATIONS AND USAGE

Treatment of Hypoprothrombinemia Due to Vitamin K Deficiency or Interference

Phytonadione Injectable Emulsion is indicated for the treatment of 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:

- anticoagulant-induced hypoprothrombinemia caused by coumarin or indanedione derivatives;
- 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.

Prophylaxis and Treatment of Vitamin K-Deficiency Bleeding in Neonates

Phytonadione Injectable Emulsion is indicated for prophylaxis and treatment of vitamin K-deficiency bleeding in neonates.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Whenever possible, administer Phytonadione Injectable Emulsion by the subcutaneous route *[see Boxed Warning]*. When intravenous administration is unavoidable, inject the drug very slowly, not exceeding 1 mg per minute.

Monitor international normalized ratio (INR) regularly and as clinical conditions indicate. Use the lowest effective dose of Phytonadione Injectable Emulsion.

The coagulant effects of Phytonadione Injectable Emulsion are not immediate; improvement of INR may take 1-8 hours. Interim use of whole blood or component therapy may also be necessary if bleeding is severe.

When Phytonadione Injectable Emulsion 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. Phytonadione Injectable Emulsion is not a clotting agent, but overzealous therapy with Phytonadione Injectable Emulsion may restore conditions which originally permitted thromboembolic phenomena. Dosage should be kept as low as possible, and INR should be checked regularly as clinical conditions indicate.

Recommended Dosage for Coagulation Disorders from Vitamin K Deficiency or Interference

The recommended dosage of Phytonadione Injectable Emulsion is based on whether the hypoprothrombinemia is anticoagulant-induced (e.g., due to coumarin or indanedione derivatives) or non-anticoagulant-induced (e.g., due to antibiotics; salicylates or other drugs; factors limiting absorption or synthesis) as follows:

- Anticoagulant-Induced Hypoprothrombinemia: Phytonadione Injectable Emulsion 2.5 mg to 10 mg or more subcutaneously, intramuscularly, or intravenously. Up to 25 mg to 50 mg may be administered as a single dose.

Repeated large doses of Phytonadione Injectable Emulsion are not warranted in liver disease if the initial response is unsatisfactory. Failure to respond to Phytonadione Injectable Emulsion may indicate that the condition being treated is inherently unresponsive to Phytonadione Injectable Emulsion.

- Hypoprothrombinemia Due to Other Causes (Non-Anticoagulation-Induced Hypoprothrombinemia): Phytonadione Injectable Emulsion 2.5 mg to 25 mg or more intravenously, intramuscularly, or subcutaneously. Up to 50 mg may be administered as a single dose.

Evaluate INR after 6-8 hours, and repeat dose if INR remains prolonged. Modify subsequent dosage (amount and frequency) based on the INR or clinical condition.

Recommended Dosage for Prophylaxis and Treatment of Vitamin K Deficiency Bleeding in Neonates

Prophylaxis of Vitamin K-Deficiency Bleeding in Neonates

The recommended dosage of Phytonadione Injectable Emulsion is 0.5 mg to 1 mg within one hour of birth for a single dose.

Treatment of Vitamin K-Deficiency Bleeding in Neonates

The recommended dosage of Phytonadione Injectable Emulsion is 1 mg given either subcutaneously or intramuscularly.

Consider higher doses if the mother has been receiving oral anticoagulants.

A failure to respond (shortening of the INR in 2 to 4 hours) may indicate another diagnosis or coagulation disorder.

Directions for Dilution

Dilute Phytonadione Injectable Emulsion with 0.9% Sodium Chloride Injection, 5% Dextrose Injection, or 5% Dextrose and Sodium Chloride Injection.

When diluted, start administration of Phytonadione Injectable Emulsion immediately after dilution.

Discard unused portions of diluted solution as well as unused contents of the vial.

Protect Phytonadione Injectable Emulsion from light at all times.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

CONTRAINDICATION

Hypersensitivity to phytonadione or any other component of this medication.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Fatal and severe hypersensitivity reactions, including anaphylaxis, have occurred with intravenous or intramuscular administration of Phytonadione Injectable Emulsion. Reactions have occurred despite dilution to avoid rapid intravenous infusion and upon first dose. These reactions have included shock, cardiorespiratory arrest, flushing, diaphoresis, chest pain, tachycardia, cyanosis, weakness, and dyspnea. Administer Phytonadione Injectable Emulsion subcutaneously whenever feasible. Avoid the intravenous and intramuscular routes of administration unless the subcutaneous route is not feasible and the serious risk is justified.

Cutaneous Reactions

Parenteral administration of vitamin K replacements (including Phytonadione Injectable Emulsion) may cause cutaneous reactions. Reactions have included eczematous reactions, scleroderma-like patches, urticaria, and delayed-type hypersensitivity reactions. Time of onset ranged from 1 day to a year after parenteral administration. Discontinue Phytonadione Injectable Emulsion for skin reactions and institute medical management.

ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions]
- Cutaneous Reactions

Clinical Trials and Post-Marketing Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following adverse reactions have been identified during post-approval use of Phytonadione Injectable Emulsion. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiac Disorders: Tachycardia, hypotension.

General disorders and administration site conditions: Generalized flushing; pain, swelling, and tenderness at injection site.

Hepatobiliary Disorders: Hyperbilirubinemia

Immune System Disorders: Fatal hypersensitivity reactions, anaphylactic reactions.

Neurologic: Dysgeusia, dizziness.

Pulmonary: Dyspnea.

Skin and Subcutaneous Tissue Disorders: Erythema, pruritic plaques, scleroderma-like lesions, erythema perstans.

Vascular: Cyanosis.

DRUG INTERACTIONS

Anticoagulants

Phytonadione Injectable Emulsion may induce temporary resistance to prothrombin-depressing anticoagulants, especially when larger doses of Phytonadione Injectable Emulsion are used. Should this occur, higher doses of anticoagulant therapy may be needed when resuming anticoagulant therapy, or a change in therapy to a different class of anticoagulant may be necessary (i.e., heparin sodium).

Phytonadione Injectable Emulsion does not affect the anticoagulant action of heparin.

OVERDOSAGE

Hemolysis, jaundice, and hyperbilirubinemia in newborns, particularly in premature infants, may result from Phytonadione Injectable Emulsion overdose.

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