

VET ONE

Distributed by MWI Animal Health

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VITAMIN K-1 INJECTION



VetOne

Phytonadione 10 mg/mL

Sterile Solution

Aqueous Colloidal

For Animal Use Only

DESCRIPTION:

Phytonadione is a vitamin, which is a clear, yellow to amber, viscous, odorless or nearly odorless liquid. It is insoluble in water, soluble in chloroform and slightly soluble in ethanol. It has a molecular weight of 450.70.

Phytonadione is 2-methyl-3-phytyl-1, 4-naphthoquinone. Its empirical formula is C₃₁H₄₆O₂.

Vitamin K-1 Injection is a yellow, sterile, aqueous colloidal solution of vitamin K1, with a pH of 5.0 to 7.0, available for injection by the intravenous, intramuscular, and subcutaneous routes. Each milliliter contains:

Phytonadione	10 mg
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Inactive ingredients:

Polyoxyethylated fatty acid derivative	70 mg
Dextrose	37.5 mg
Water for Injection, q.s.	1 mL

Added as preservative:

Benzyl alcohol	1.5% v/v
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CLINICAL PHARMACOLOGY:

Vitamin K-1 Injection aqueous colloidal solution of vitamin K1 for parenteral injection, possesses the same type and degree of activity as does naturally-occurring vitamin K, which is necessary for the production via the liver of active prothrombin (factor II), proconvertin (factor VII), plasma thromboplastin component (factor IX), and Stuart factor (factor X). The prothrombin test is sensitive to the levels of three of these four factors-II, VII, and X. Vitamin K is an essential cofactor for a microsomal enzyme that catalyzes the posttranslational carboxylation of multiple, specific, peptide-bound glutamic acid residues in inactive hepatic precursors of factors II, VII, IX, and X. The resulting gamma-carboxyglutamic acid residues convert the precursors into active coagulation factors that are subsequently secreted by liver cells into the blood.

Phytonadione is readily absorbed following intramuscular administration. After absorption, phytonadione is initially concentrated in the liver, but the concentration declines rapidly. Very little vitamin K

accumulates in tissues. Little is known about the metabolic fate of vitamin K. Almost no free unmetabolized vitamin K appears in bile or urine.

In normal animals, phytonadione is virtually devoid of pharmacodynamic activity. However, in animals deficient in vitamin K, the pharmacological action of vitamin K is related to its normal physiological function, that is, to promote the hepatic biosynthesis of vitamin K dependent clotting factors.

The action of the aqueous colloidal solution, when administered intravenously, is generally detectable within an hour or two and hemorrhage is usually controlled within 3 to 6 hours. A normal prothrombin level may often be obtained in 12 to 14 hours.

INDICATIONS:

Vitamin K-1 Injection is indicated in 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 K-1 Injection is indicated in cattle, calves, horses, swine, sheep, goats, dogs, and cats to counter hypoprothrombinemia induced by ingestion of anticoagulant rodenticides.

Vitamin K-1 Injection is also indicated to counter hypoprothrombinemia caused by consumption of bishydroxycoumarin found in spoiled and moldy sweet clover.

DOSAGE AND ADMINISTRATION:

Cattle, Calves, Horses, Swine, Sheep, and Goats: Acute hypoprothrombinemia (with hemorrhage) and Non-acute hypoprothrombinemia - 0.5-2.5 mg/kg subcutaneously OR intramuscularly.

Dogs and Cats: Acute hypoprothrombinemia (with hemorrhage) and Non-acute hypoprothrombinemia - 0.25-5 mg/kg subcutaneously or intramuscularly. Use higher end of dose for second generation rodenticides.

Whenever possible, **Vitamin K-1 Injection** should be given by the subcutaneous or intramuscular route. When intravenous administration is considered unavoidable, the drug should be diluted and injected very slowly, not exceeding 1 mg per minute.

Direction For Dilution:

Vitamin K-1 Injection may be diluted with 0.9% Sodium Chloride Injection, 5% Dextrose Injection, or 5% Dextrose and Sodium Chloride Injection. Other Diluents Should Not Be Used. When dilutions are indicated, administration should be started immediately after mixture with diluent, and unused portions of the dilution should be discarded.

Whole blood or component therapy may be indicated if bleeding is excessive. This therapy, however, does not correct the underlying disorder and **Vitamin K-1 Injection** should be given concurrently. In the event of shock or excessive blood loss, the use of whole blood or component therapy is indicated.

CONTRAINDICATIONS:

Hypersensitivity to any component of this medication.

PRECAUTIONS:

Drug Interactions:

Temporary resistance to prothrombin-depressing anticoagulants may result, especially when larger doses of phytonadione are used. If relatively large doses have been employed, it may be necessary when reinstating 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.

Laboratory Tests - Prothrombin time should be checked regularly as clinical conditions indicate.

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

CAUTIONS:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

WARNINGS:

WARNING-INTRAVENOUS USE - Severe reactions, including fatalities, have occurred during and immediately after INTRAVENOUS injection of phytonadione, even when precautions have been taken to dilute the phytonadione and to avoid rapid infusion. Typically these severe reactions have resembled hypersensitivity or anaphylaxis, including shock and cardiac and/or respiratory arrest. Some patients have exhibited these severe reactions on receiving phytonadione for the first time. Therefore the INTRAVENOUS route should be restricted to those situations where other routes are not feasible and the serious risk involved is considered justified.

An immediate coagulant effect should not be expected after administration of phytonadione. *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.

Phytonadione 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. Phytonadione 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.

ADVERSE REACTIONS:

Deaths have occurred after intravenous administration. **(SEE WARNING ABOVE.)**

Pain, swelling, and tenderness at the injection site may occur. Intramuscular injection may result in hematomas.

The possibility of allergic sensitivity, including an anaphylactoid reaction, should be kept in mind.

STORAGE:

Protect from light at all times. Store in dark place.

Store at controlled room temperature 15°-30°C (59°-86°F)

HOW SUPPLIED: 100mL vial

For use in animals only.

Keep out of reach of children.

Distributed by: MWI, Boise, ID 83705

(888) 694-8381

www.vetone.net

MADE IN USA

Net Contents:	NDC:	
100 mL	13985-053-95	V1 501051

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