VETA-K1- phytonadione solution
Bimeda Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Veta-K_1® Injection

(phytonadione)

Aqueous Colloidal Solution

10 mg/mL

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law restricts this drug to use by or on the order of a lincensed veterinarian

Net Contents: 100 mL

Multiple Dose Vial

For complete warnings and additional information see enclosed insert.

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.

Veta-K_1® Injection is a yellow, sterile, aqueous colloidal solution of vitamin K_1, with a pH of 5.0 to 7.0, available for injection by the intravenous, intramuscular and subcutaneous routes.

EACH mL CONTAINS: Phytonadione 10 mg; Polyoxyethylated fatty acid derivative 65 mg; Dextrose monohydrate 37.5 mg; Butylated hydroxyanisole 1 mg; Butylated hydroxytoluene 1 mg; Citric acid 8.4 mg; Sodium phosphate 17.2 mg; with Benzyl Alcohol 0.9% w/v added as a preservative.

CLINICAL PHARMACOLOGY:

Veta-K_1® Injection aqueous colloidal solution of vitamin K_1 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 post-translational carboxylation of multiple, specific, peptide-bound glutamic acid residues in inactive hepatic precursors of factors II, VII, IX, and X. The resulting gamma-carboxy-glutamic 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 and humans, phytonadione is virtually devoid of pharmacodynamic activity. However, in animals and humans 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: Veta-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.

Veta-K_1® Injection is also indicated in cattle, calves, horses, swine, sheep, goats, dogs, and cats to counter hypoprothrombinemia induced by ingestion of anticoagulant rodenticides. Veta-K_1® Injection is also indicated to counter hypoprothrombinemia caused by consumption of bishydroxycoumarin found in a 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 - 5.0 mg/kg subcutaneously OR intramuscularly. Use higher end of dose for second generation rodenticides.

Whenever possible, Veta-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.

DIRECTIONS FOR DILUTION: Veta-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 the 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 Veta-K_1® Injection should be given concurrently. In the event of shock or excessive blood loss, the use of whole blood 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 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.

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.

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WARNING:

WARNING - INTRAVENOUS USE: Severe reactions, including fatalities, have occurred during and immediately after the 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 animals 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. *A minimum of 1 to 2 hours is required for measurable improvement in the prothrombin time.* Whole blood or component therapy may also be necessary if bleeding is severe.

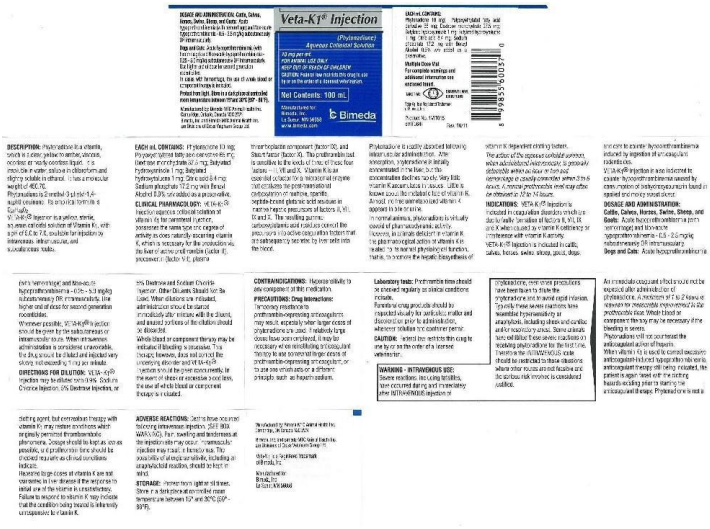
Phytonadione will not counteract the anticoagulant action of heparin.

When vitamin K_1 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 K_1 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 occured following intravenous injection. (SEE BOX WARNING). 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 a dark place at controlled room temperature between 15° and 30° C (59° - 86° F).



VETA-K1

phytonadione solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:61133-6003
Route of Administration	SUBCUTANEOUS, INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	10 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61133-6003-1	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/07/2005	

Labeler - Bimeda Inc. (060492923)

Registrant - Bimeda Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC		256232216	manufacture

Revised: 12/2018 Bimeda Inc.