VITAMIN K1 INJECTABLE- phytonadione injection
Neogen Corporation - Nandino

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.

NeogenVet Vitamin K1 Injection

FOR ANIMAL USE ONLY

Each mL contains:

Phytonadione.....10 mg

Emulphor EL-719.....70 mg

Dextrose H_2O.....41.2 mg

Benzyl Alcohol (preservative).....1.5%

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

Protect from light - store in a dark place. Store at controlled room temperature between 15°-30°C (59°-86°F).

Rev. 7-09

V-0681-04

Item No. 09089

Principal Display Panel Vitamin K1 Injection 100 mL

NDC: 59051-9089-5

Vitamin K1 Injections

(Phytonadione) 10 mg/mL

Aqueous Colloidal

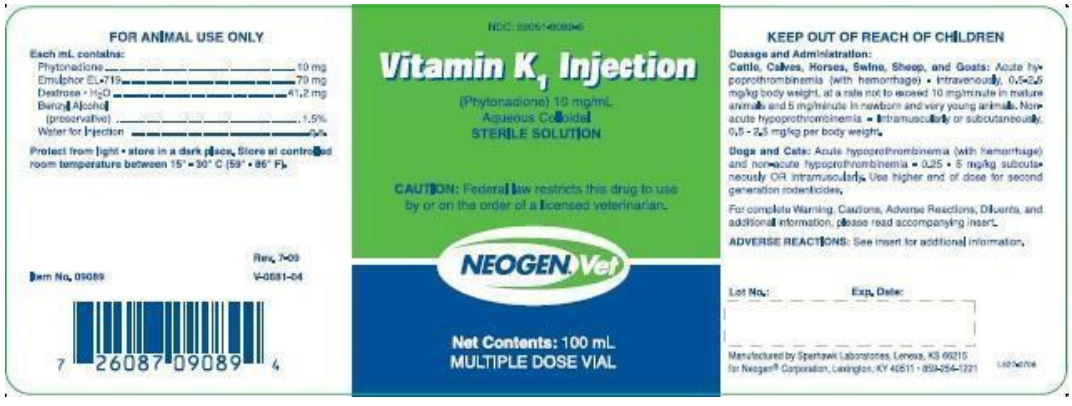
STERILE SOLUTION

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

NEOGEN.Vet

Net Contents: 100 mL

MULTIPLE DOSE VIAL



KEEP OUT OF REACH OF CHILDREN

Dosage and Administration:

Cattle, Calves, Horses, Swine, Sheep, and Goats: Acute hypotrothrombinemia (with hemorrhage):

intravenously, 0.5-2.5 mg/kg body weight, at a rate not to exceed 10 mg/minute in mature animals and 5 mg/minute in newborn and very young animals. Non-acute hypoprothrombinemia: intramuscularly or subcutaneously, 0.5-2.5 mg/kg per body weight.

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

ADVERSE REACTIONS: See insert for additional information.

Manufactured by Sparhawk laboratories, Lenexa, KS 66215

for Neogen®Corporation, Lexington, KY 40511 859-254-1221

Package Insert

VITAMIN K_1

(Phytonadione)

Injection

Vitamin K Injection

(Phytonadione)

Aqueous Colloidal Solution of Vitamin K_1

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 Vitamin K_1 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 Vitamin K_1 Injection 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.

See ADVERSE REACTION section for possible Intramuscular and Subcutaneous reactions.

DESCRIPTION: Vitamin K_1 Injection is a yellow, sterile acqueous colloidal solution of Vitamin K_1 (phytonadione), available for injection by the intravenous, intramuscular and subcutaneous routes. Each mL contains:

Phytonadione.....10 mg

Inactive Ingredients

Emulphor EL-719.....70 mg

Dextrose H_2O.....41.2 mg

Water.....q.s.

Added as a preservative

Benzyl Alcohol.....1.5%

ACTIONS: Vitamin K_1 Injection, an aqueous colloidal solution of Vitamin K_1 for parenteral injection, possesses the same type and degree of activity as does naturally occurring Vitamin K. The primary function of vitamin K is to stimulate the production via the liver of active prothrombin from a precursor protein. The mechanism by which vitamin K promotes formation of prothrombin at the molecular level has not been established. 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 cattle, calves, horses, swine, sheep, goats, dogs and cats to counter Hypoprothrombinemia induced by ingestion of coumarin-based compounds, common ingredients in commercial rodenticides. Vitamin K_1 Injection is also indicated to counter hypoprothrombinemia caused by consumption of Bishydroxycoumarin found in spoiled and moldy sweet clover.

NOTE: Regualr determinations of prothrombin time response should be performed to guide in the

initial and subsequent administration of Vitamin K_1 Injection. The dosage should be adjusted accordingly.

CONTRAINDICATIONS: Hypersensitivity to any component of this medication.

WARNINGS: 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 be necessary if the bleeding is severe.

Phytonadione will not counteract the anticoagulant action of heparin.

Repeated large doses of vitamin K are not warranted in hepatic disease if the response to the initial therapy is unsatisfactory. Failure to respond to vitamin K may indicate that the condition being treated is inherently unresponsive to vitamin K.

VITAMIN K1 INJECTABLE

phytonadione injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:59051-9089
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
DEXTROSE (UNII: IY9XDZ35W2)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59051-9089-5	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		11/27/2012	

Labeler - Neogen Corporation - Nandino (042125879)

Establishment

Name	Address	ID/FEI	Business Operations
Sparhawk		147979082	manufacture, analysis, sterilize

Revised: 11/2012 Neogen Corporation - Nandino