Vitamin K1 Laboratoire TVM 50 mg film-coated tablets for dogs

Species: Dogs
Therapeutic indication: **Pharmaceuticals:** Miscellaneous
Active ingredient: Phytomenadione
Product: Vitamin K1 Laboratoire TVM 50 mg film-coated tablets for dogs
Product index: Vitamin K1 Laboratoire TVM 50 mg film-coated tablets for dogs

Presentation

Each film-coated tablet contains 50mg phytomenadione. A slight yellow oblong tablet with 3 scored lines. The tablet can be divided into halves and quarters.

Uses

Treatment of anticoagulant poisoning, following parenteral treatment, in dogs.

Dosage and administration

For oral use.

5 mg phytomenadione per kg bodyweight per day, corresponding to 1 tablet per 10 kg bodyweight per day, once a day, for 21 days, in accordance with the following table:

Bodyweight (kg)	Number of tablets
≤ 2.5	*¼ tablet*
from 2.5 to 5	*½ tablet*
from 5 to 7.5	*¾ tablet*
*from 7.5 to 10**	*1 tablet*

* *Dog ≥ 10 kg: ¼ tablet per 2.5 kg*

Preferably use in non-fasted animals. Oral treatment should be undertaken within 12 hours after the end of the emergency treatment by the intravenous route (2 intravenous injections of 5 mg vitamin K1 per kg bodyweight given 12 hours apart). (see warnings section).

Contra-indications, warnings, etc

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

Adverse reactions: Very rarely, vomiting and skin disorders, as erythema and dermatitis,

or allergic edema have been reported.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Special warnings: As the anticoagulant effects of rodenticides are known to be long lasting it is recommended to administer vitamin K1 with an oral formulation for 3 weeks. The coagulation status (via one stage prothrombin times) has to be evaluated 48 hours after the last administration. If it is prolonged, the treatment is maintained until the clotting time is normal 48 hours after cessation of treatment to avoid relapse. The duration of treatment can be extended as long as the anticoagulant persists in the body.

The formation of prothrombin may be inadequate when dealing with patients with severe liver dysfunction. Therefore, in these animals, careful monitoring of coagulation parameters after administration of the product is required.

The safety of the veterinary medicinal product has not been established in bitches during pregnancy and lactation. Studies conducted in laboratory animals have shown no teratogenic or foetotoxic effects. Vitamin K1 crosses the placental barrier. Use only according to the benefit/risk assessment by the responsible veterinarian.

User precautions: People with known hypersensitivity to phytomenadione should avoid contact with the veterinary medicinal product.

Wash hands after use.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.

Pharmaceutical precautions

Store in the original packaging, protect from light.

After opening the blister pocket, replace the remaining portion(s) of tablet in the blister pocket and return the blister strip to the cardboard carton.

A remaining tablet portion should be given at the next administration.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Legal category

Legal category:NFA-VPS

Packaging quantities

Immediate packaging - box containing white PVC/Aluminium thermosealed blister packs

of 14 tablets.

Marketing Authorisation Holder (if different from distributor)

Laboratoire TVM

57 rue des Bardines

63370 Lempdes

France

Further information

Salicylates (NSAID) and cephalosporins presenting the N-methyl-thiotetrazole moiety may reduce the effect of vitamin K1, by inhibition of the vitamin K1 recycling.

No signs of intolerance were displayed at 3 times the therapeutic dose, administered for 3 weeks.

Vitamin K1 is a cofactor necessary for the synthesis of K-dependent coagulation factors (factors II, VII, IX and X). During this synthesis, vitamin K1 is converted into vitamin K1 hydroquinone (active form of vitamin K1) and then into vitamin K1 epoxide. It is then recycled back into vitamin K1. Antivitamin K rodenticides inhibit the recycling of vitamin K1 epoxide, causing a risk of uncontrolled bleeding through the absence of functional factors II, VII, IX and X synthesis. The supply of vitamin K1 must be sufficiently large to activate the alternative hydrogenase enzyme pathway that converts it to its active (hydroquinone) form.

After oral administration, vitamin K1 is rapidly absorbed in the dog.

Some of the vitamin K1 is eliminated with the bile in the intestinal tract after metabolism in the liver, and some is eliminated in urine (in the form of glucuronoconjugated metabolites).

Marketing Authorisation Number

Vm 35079/4001

Significant changes

GTIN

GTIN description:--
GTIN:--
TVM Animal Health Ltd
Telephone:0800 0385868
Website:www.tvm-uk.com
Email:help@tvm-uk.com