SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamin K1 Laboratoire TVM 50 mg Film-coated Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each divisible tablet contains:

Active substance:
Phytomenadione ..... 50.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Oblong tablet, slight yellow with 3 scored lines.
The tablet can be divided into halves and quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

In dogs: treatment of anticoagulant poisoning, following parenteral treatment.

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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 section 4.4.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC-vet code: QB02BA01
Pharmacotherapeutic classification: antihaemorrhagic

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Silica, colloidal anhydrous
Calcium hydrogen phosphate dihydrate
Glycerol dibehenate
Magnesium stearate
Lactose monohydrate
Croscarmellose sodium

Coating:
Hypromellose
Polydextrose
Talc
Maltodextrine
Medium Chain Triglycerides

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life of any divided tablets: 3 days.

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

Box containing white PVC/Aluminium thermosealed blister of 7 tablets each.

Box of 1 thermosealed blisters of 7 tablets
Box of 2 thermosealed blisters of 7 tablets
Box of 3 thermosealed blisters of 7 tablets
Box of 4 thermosealed blisters of 7 tablets
Box of 5 thermosealed blisters of 7 tablets
Box of 12 thermosealed blisters of 7 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Domes Pharma SC
57 rue des Bardines
63370 Lempdes
France

8. MARKETING AUTHORISATION NUMBER

Vm 35079/4001

9. DATE OF FIRST AUTHORISATION

26 March 2013

10. DATE OF REVISION OF THE TEXT

March 2021

Approved 17 March 2021