SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 50 mg Film-coated Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each divisible tablet contains:

Active substance:
Phytomenadione ..... 50,0 mg

Excipients:

Qualitative composition of excipients and other constituents
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

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

3. CLINICAL INFORMATION

3.1 Target species

Dog

3.2 Indications for use for each target species

Treatment of anticoagulant poisoning, following parenteral treatment.

3.3 Contraindications

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

3.4 Special warnings

As the anticoagulant effects of rodenticides are known to be long lasting it is recommended to administer Vitamivet 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting Skin disorder (e.g. erythema and dermatitis) Allergic edema

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the section ‘Contact Details’ of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation
Use only according to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies have shown not produced any evidence of teratogenic or fœtotoxic effects. Vitamivet K1 crosses the placental barrier.

3.8 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 Vitamivet K1, by inhibition of the Vitamivet K1 recycling.

3.9 Administration routes and dosage

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 Vitamivet K1 per kg bodyweight given 12 hours apart). See section 3.4.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

[For MRP/DCP/SRP and national procedures: To be completed nationally.]

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB02BA01

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

After oral administration, Vitamivet K1 is rapidly absorbed in the dog.
Some of the Vitamivet 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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable

5.2 Shelf life

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

5.3 Special precautions for storage

Keep the blisters in the outer carton. 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.

5.4 Nature and composition of immediate packaging

Cardboard 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

7. MARKETING AUTHORISATION NUMBER

Vm 54982/3004

8. DATE OF FIRST AUTHORISATION

26 March 2013

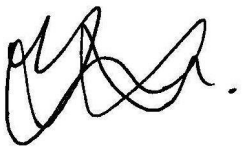
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).



Approved: 22 June 2023