SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 10 mg/ml Solution for Injection for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains:

Active substance:
Phytomenadione ..... 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycocholic acid
Lecithin (soya bean)
Sodium hydroxide
Hydrochloric acid
Water for injections

Solution for injection
Yellow, clear to slightly opalescent liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dog

3.2 Indications for use for each target species

Emergency treatment of anticoagulant rodenticide poisoning, before starting oral 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 start vitamin K1 supplementation with an oral formulation within 12

hours of the last injection for a duration of 3 weeks, and to evaluate the coagulation status (via one stage prothrombin times) 48 hours after the last administration. In the case of persistence of the anticoagulant in the body, the duration of treatment can be extended as long as the anticoagulant persists, to avoid relapse (the coagulation status has to be evaluated 48 hours after each attempt of treatment cessation).

3.5 Special precautions for use

Special precautions for safe use in the target species:
Administer by slow intravenous injection.
The formation of prothrombin may be inadequate when dealing with patients with severe liver dysfunction. Therefore requires a careful monitoring of coagulation parameters after administration of vitamin K1.

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.
Avoid contact with eye. In the event of accidental contact with eye, rinse immediately and thoroughly with tap water, then seek a doctor and show the label to the physician.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency	Hypersensitivity reactions (anaphylactic-type reactions)

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 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 accordingly to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies have shown not produced any evidence of teratogenic or fœtotoxic effects. Vitamin 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 vitamin K1, by inhibition of the vitamin K1 recycling.

3.9 Administration routes and dosage

Intravenous use

Slow injection of 5 mg vitamin K1 per kg bodyweight (equivalent to 0.5 ml of the veterinary medicinal product per kg bodyweight) prior to commencing oral therapy (see section 3.4). Treatment by injection should be repeated once 12-18 hours later if oral treatment is not immediately possible.

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

Vomiting has been observed in the dog after the 1st and the 2nd injections, administered 12 hours apart at 3 times the recommended dose (15 mg of vitamin K1 per kg of body weight per injection).
Repeating dosing (10 days) at 7 times the recommended dose of a degraded solution (degradation of lecithin into lysolecithin is observed with time during the storage of the veterinary medicinal product) caused intravascular haemolysis, involving marked anaemia and vomiting.

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 administration only by a veterinarian.
[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

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 hydrogenase enzyme that converts it to its active (hydroquinone) form.

4.3 Pharmacokinetics

After intravenous administration at 5 mg/kg in the dog, the following pharmacokinetic parameters were obtained:
Cmax = 85.2 µg/ml, AUC = 4246 µg.min./ml, T1/2 = 179.5 min., Cl = 1.15 ml/min., a bioavailability of 100 % and a distribution volume estimated at 4 ×10-4 ml.
One hour after intravenous administration, vitamin K1 is detected in the liver (90% unchanged) before being distributed throughout the body.
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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Protect from light.
Store below 25°C.
Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

5.4 Nature and composition of immediate packaging

5ml amber clear glass ampoules, type I.
Cardboard box of 6 ampoules of 5 ml

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
3 Rue Andre Citroën
63430 Pont-Du-Chateau
France

7. MARKETING AUTHORISATION NUMBER

Vm 54982/3003

8. DATE OF FIRST AUTHORISATION

20 April 2010

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

August 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 11 August 2023