ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 10 mg/ml Solution for Injection for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:
Phytomenadione ..... 10,0 mg

3. PACKAGE SIZE

6x5ml

4. TARGET SPECIES

Dog

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {month/year}
Once open use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C. Protect from light. Store in the original package.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Domes Pharma
3 Rue Andre Citroën
63430 Pont-Du-Chateau
France

14. MARKETING AUTHORISATION NUMBERS

Vm 54982/3003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ampoules}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 10 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {month/year}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vitamivet K1 10 mg/ml Solution for Injection for Dogs

2. Composition

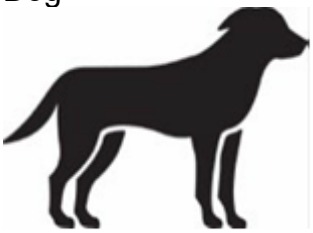
Each ml of solution contains:

Active substance:
Phytomenadione ..... 10,0 mg

Solution for injection
Yellow, clear to slightly opalescent liquid.

3. Target species

Dog



4. Indications for use

Emergency treatment of anticoagulant rodenticide poisoning, before starting oral treatment.

5. Contraindications

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

6. Special warnings

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).

Special precautions for safe use in animals:
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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian. Laboratories studies have shown not produced any evidence of teratogenic or fœtotoxic effects. Vitamin K1 crosses the placental barrier.

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.

Overdose:
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.

Special restriction for use and special conditions for use:
For administration only by a veterinarian.

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

7. Adverse events

Dogs :

Undetermined frequency :
Hypersensitivity reactions (anaphylactic-type reactions)

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to either the marketing authorisation holder or the local representative of the marketing

authorisation holder using the contact details at the end of this leaflet, or via your national reporting system <{national system details}.>

8. Dosage for each species, routes and method of administration

Slow intravenous 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 special warnings). Treatment by injection should be repeated once 12-18 hours later if oral treatment is not immediately possible.

9. Advice on correct administration

Administer by slow intravenous injection.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Store below 25°C.
Protect from light.
Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.
Keep out of the reach and sight of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: Use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:

Vm 54982/3003

Pack sizes:
Cardboard box of 6 ampoules of 5 ml.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
DOMES PHARMA
3 RUE ANDRE CITROEN
63430 PONT-DU-CHATEAU
FRANCE

Manufacturer responsible for batch release:
CENEXI
52 Rue Marcel et Jacques Gaucher
94120 FONTENAY-SOUS-BOIS
FRANCE

<Local representatives <and contact details to report suspected adverse reactions> :>:
<For any information about this veterinary medicinal product, please contact the local representative of the marketing autorisation holder listed below.>
National information

17. Other information

Adverse reaction (except for FR leaflet)
Since this veterinary medicinal product does not contain polyethoxylated castor oil (Cremophor), the substance responsible for anaphylactic reactions following intravenous administration of other preparations, the veterinary medicinal product is suitable for administration by this route.

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

Approved 11 August 2023