PARTICULARS TO APPEAR ON THE OUTER PACKAGE { Cardboard box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 10 mg/ml Solution for Injection for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution ml contains:

Active substance:
Phytomenadione 10.0 mg

3. PACKAGE SIZE

6 x 5 ml.

4. TARGET SPECIES

Dog

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Domes Pharma

3 Rue Andre Citroën

63430 Pont-Du-Chateau

France

Local representatives:

TVM UK ANIMAL HEALTH LTD

United Kingdom

Custumer service : help@tvm-uk.com

14. MARKETING AUTHORISATION NUMBERS

Vm 54982/5003.

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {ampoules}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 10 mg/ml Solution for Injection for Dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 WARNING(S)

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 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.

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 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.

Major incompatibilities:

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

Special restriction for use and special conditions for use:

For administration only by a veterinarian.

For Animal Treatment Only

Keep out of sight and reach of children.

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, ROUTE(S) AND METHOD OF ADMINISTRATION

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 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 PERIOD(S)

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.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number: Vm 54982/5003.

Pack sizes:

Cardboard box of 6 ampoules of 5 ml.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

16. CONTACT DETAILS

Marketing authorisation holder

Domes Pharma

3 Rue Andre Citroën

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 reacions :

TVM UK ANIMAL HEALTH LTD

United Kingdom

Custumer service : help@tvm-uk.com

Approved 11 August 2023