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 50 mg Film-coated Tablets for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each divisible tablet contains:

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

3. PACKAGE SIZE

7 tablets
14 tablets
21 tablets
28 tablets
35 tablets
84 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {month/year}

9. SPECIAL STORAGE PRECAUTIONS

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.

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

14. MARKETING AUTHORISATION NUMBER

Vm 54982/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1 50 mg Film-coated Tablets for Dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg

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 50 mg Film-coated Tablets for Dogs

2. Composition

Each divisible tablet contains:

Active substance:
Phytomenadione ..... 50.0 mg

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

3. Target species

Dog

4. Indications for use

Treatment of anticoagulant poisoning, following parenteral 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 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.

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.

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

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

7. Adverse events

Dogs:

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

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

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 “Special warnings”.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach or children.
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.

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

Shelf-life of any divided tablets: 3 days.

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.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:
Vm 54982/3004

Pack sizes:
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.

15. Date on which the package leaflet was last revised

April 2023

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

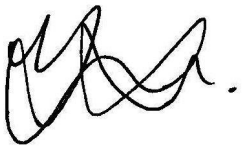
Manufacturer responsible for batch release:
EUROPHARTECH
RUE HENRI MATISSE
63370 LEMPDES
FRANCE

<For any information about this veterinary medicinal product, please contact the local representative of the marketing autorisation holder listed below.>

<Local representatives <and contact details to report suspected adverse reactions> :>:

17. Other information

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



Approved: 22 June 2023