SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1, 10 mg/ml solution for injection for dogs (UK(NI))
Vitamivet K1, 10 mg/ml Injektionslösung für Hunde (AT, DE)
Vitamivet K1, 10 mg/ml, Oplossing voor injectie voor honden (NL)
Vitamivet K1, 10 mg/ml, solution injectable pour chiens (FR)
Vitamivet K1, 10 mg/ml, soluzione iniettabile per cani,(IT)
Vitamivet K1, 10 mg/ml, solución inyectable para perros (ES)

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

7. MARKETING AUTHORISATION NUMBER(S)

AT: Zul.-Nr.:8-00937
DE : Zul.-Nr.:401293.00.00
NL: REG NL 105144
IT: AIC 104187
ES : 2144 ESP
FR : FR/V/0892879 3/2007
UK(NI) : Vm 54982/3003

8. DATE OF FIRST AUTHORISATION

AT: 24/02/2011
DE : 04/11/2009
NL: 22/02/2010
IT: 05/07/2010
ES: 13/04/2010
FR: 03/05/2007
UK : 20/04/2010

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

XX/XX/XXXX

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).

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 (UK(NI))
Vitamivet K1, 10 mg/ml Injektionslösung für Hunde (AT, DE)
Vitamivet K1, 10 mg/ml, Oplossing voor injectie voor honden (NL)
Vitamivet K1, 10 mg/ml, solution injectable pour chiens (FR)
Vitamivet K1, 10 mg/ml, soluzione iniettabile per cani,(IT)
Vitamivet K1, 10 mg/ml, solución inyectable para perros (ES)

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

14. MARKETING AUTHORISATION NUMBERS

AT: Zul.-Nr.:8-00937
DE : Zul.-Nr.:401293.00.00
NL: REG NL 105144
IT: AIC 104187
ES : 2144 ESP
FR : FR/V/0892879 3/2007
UK : Vm 54982/4003

15. BATCH NUMBER

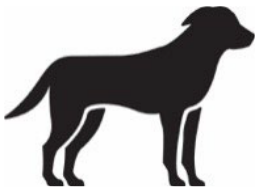
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ampoules}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamivet K1, (AT, DE, UK(NI))
Vitamivet K1, (FR)
Vitamivet K1, (ES, IT)



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 (UK(NI))
Vitamivet K1, 10 mg/ml Injektionslösung für Hunde (AT, DE)
Vitamivet K1, 10 mg/ml, Oplossing voor injectie voor honden (NL)
Vitamivet K1, 10 mg/ml, solution injectable pour chiens (FR)
Vitamivet K1, 10 mg/ml, soluzione iniettabile per cani,(IT)
Vitamivet K1, 10 mg/ml, solución inyectable para perros (ES)

2. Composition

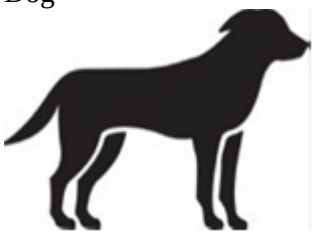
Each ml of solution contains:

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 numbers:
AT: Zul.-Nr.:8-00937
DE : Zul.-Nr.:401293.00.00
NL: REG NL 105144
IT: AIC 104187
ES : 2144 ESP
FR : FR/V/0892879 3/2007
UK : Vm 54982/4003

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

15. Date on which the package leaflet was last revised

XX/XXXX

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.]”