1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamin K1 10 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Phytomenadione 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Polyoxyl Castor Oil	
Benzyl Alcohol (preservative)	9.0 mg
Butylhydroxyanisole (antioxidant)	1.0 mg
Butylhydroxytoluene (antioxidant)	1.0 mg
Anhydrous Citric Acid	
Sodium Phosphate	
Glucose Monohydrate	
Water for Injections	

A clear, pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Domestic animals.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of hypoprothrombinaemia associated with poisoning by warfarin or other coumarins.

3.3 Contraindications

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

3.4 Special warnings

Acute haemorrhage may also require transfusion therapy. Phytomenadione will not counteract the anticoagulant action of heparin.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Intravenous injections should be administered slowly.
If separation has occurred or if oil droplets have appeared, the veterinary medicinal product should not be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Domestic animals:

Undetermined frequency (cannot be estimated from the available data)	Anaphylactoid reactions[1], Hypersensitivity reactions[1], Unexplained death[2], Injection site pain, Injection site swelling

[1]May occur following intravenous administration.
[2]Fatalities have occurred with products of this kind although it is unclear whether these reactions were caused by phytomenadione itself or by surfactants included in the formulation.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Vitamin K1 does not appear to cross the placenta readily. The risks of vitamin K1 administration to the foetus are not significant in the context of potentially fatal haemorrhage due to coumarin poisoning.

3.8 Interaction with other medicinal products and other forms of interaction

As vitamin K1 possibly acts by competitive antagonism of coumarins, the efficacy of vitamin K1 will be reduced by continued dosage of coumarins.

3.9 Administration routes and dosage

By intramuscular, subcutaneous or slow intravenous injection.

Dogs and cats: 0.25 - 2.5 mg/kg body weight.
Large animals: 0.5 - 2.5 mg/kg body weight.
Daily dosing should continue for four days.

In severe cases of anaemia, the dosage may be increased to 5 mg/kg body weight for 4 days followed by oral vitamin K1 therapy.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Large doses of vitamin K1 given therapeutically to counteract coumarin derivatives administered to prevent thrombosis will expose the patient to thrombosis again.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QB02.

4.2 Pharmacodynamics

Vitamin K1 (phytomenadione) is a fat-soluble vitamin whose physiological activity stimulates final production of prothrombin (factor II). Prothrombin is an essential component of one blood coagulation process and is synthesised by the liver. The intended use of vitamin K1 is in the treatment of poisoning by warfarin or other coumarins. Large doses of vitamin K1can overcome the action of coumarins which inhibit hepatic synthesis of vitamin K1 dependent clotting factors.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 7 days.

5.3 Special precautions for storage

Do not store above 25 °C .
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

50 ml amber Type II glass, multidose vial sealed with a bromobutyl rubber bung and capped with an aluminium cap containing a clear to slightly opalescent, pale yellow, aqueous, colloidal solution for injection.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Bimeda Animal Health Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/048/001

8. DATE OF FIRST AUTHORISATION

01 October 1991

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

17/06/2025

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).