Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamin K1 10 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	per ml	
Phytomenadione	10.0	mg
Excipients		
Benzyl Alcohol (preservative)	9.0	mg
Butylhydroxyanisole (antioxidant)	1.0	mg
Butylhydroxytoluene (antioxidant)	1.0	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Domestic animals.

4.2 Indications for use, specifying the target species

Vitamin K1 Injection is indicated in the treatment of hypoprothrombinaemia associated with poisoning by warfarin or other coumarins.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
Intravenous injections should be administered slowly.
If separation has occurred or if oil droplets have appeared, the product should not be used.

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

4.6 Adverse reactions (frequency and seriousness)

Anaphylactoid and other hypersensitivity reactions may occur following intravenous administration. 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. Pain and swelling may occur at injection sites following administration of phytomenadione.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

By intramuscular, subcutaneous or slow intravenous injection.
Dogs and cats: 0.25 - 2.5 mg/kg bodyweight.
Large animals: 0.5 - 2.5 mg/kg bodyweight.
Daily dosing should continue for four days.
In severe cases of anaemia, the dosage may be increased to 5 mg/kg BW for 4 days followed by oral Vitamin K1 therapy.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat: 28 days. Animals may not be slaughtered for human consumption until 28 days after the last treatment.
Milk: 7 days. Milk may not be taken for human consumption until 7 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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 Injection is in the treatment of poisoning by warfarin or other coumarins. Large doses of Vitamin K1 can overcome the action of coumarins which inhibit hepatic synthesis of Vitamin K1 dependant clotting factors.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyl Castor Oil
Benzyl Alcohol
Butylhydroxyanisole
Butylhydroxytoluene
Anhydrous Citric Acid
Sodium Phosphate
Glucose Monohydrate
Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal Product as packaged for sale: 2 years.

Shelf-life of the after first opening the immediate packaging: 7 days after first broaching.

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 30 September 2006

10 DATE OF REVISION OF THE TEXT

June 2019