SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin vet. 10 mg/ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerol formal (contains thiopropionic acid, N-propyl gallate and disodium edetate)

Clear colourless to slightly yellow coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, reindeer and pigs.

3.2 Indications for use for each target species

This veterinary medicinal product is indicated for treatment of the following parasites of cattle, reindeer and pigs.

Cattle:
Gastrointestinal roundworms (adult and fourth stage larvae, L4)
Ostertagia ostertagi (including inhibited L4)
Ostertagia lyrata
Haemonochus placei
Trichostrongylus axei
Trichostrongylus colubriformis (L4)
Cooperia spp.
Oesophagostomum radiatum
Nematodirus spathiger (adult)

Lungworms (adult and fourth stage larvae, L4)
Dictyocaulus viviparus

Warbles (larval stages)
Hypoderma bovis
Hypoderma lineatum

Mange mites
Sarcoptes scabiei var. *bovis*
Psoroptes bovis

Lice
Linognathus vituli
Haematopinus eurysternus

Reindeer:
Warbles (larval stages)
Hypoderma tarandi

Pigs:
Gastrointestinal roundworms (adult and fourth stage larvae, L4)
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransomi (adult)

Lungworms
Metastrongylus spp. (adult)

Mange mites
Sarcoptes scabiei var. *suis*

Lice
Haematopinus suis

3.3 Contraindications

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

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or herd.

For the treatment of gastro-intestinal and respiratory nematodes:
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

3.5 Special precautions for use

Special precautions for safe use in the target species:Neonatal pigs are sensitive for overdosage of ivermectin, presumably due to a more permeable blood-brain barrier. Piglets < 5 days should not be treated.

Avermectins/milbemycins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

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

3.6 Adverse events

Cattle, reindeer and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site reaction*

*Local reaction at the injection site may occur.

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 also the 'Contact details' section of the package leaflet for respective contact details.

3.7 Use during pregnancy and lactation

Pregnancy and lactation:
The veterinary medicinal product can be administered to beef cows and pigs at any stage of pregnancy or lactation. The veterinary medicinal product should not be given to lactating cows or heifers and dry cows within 60 days prior to calving, when the milk is intended for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

Cattle and reindeer: 1 ml per 50 kg bodyweight, corresponding to 0.2 mg ivermectin per kg bodyweight.

Pigs: 1 ml per 33 kg bodyweight, corresponding to 0.3 mg ivermectin per kg bodyweight.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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

Severe overdose (4-30 mg/kg) can lead to lethargy, ataxia and tremor.

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:
Cattle: 49 days
Reindeer and pigs: 28 days

Not authorised for use in lactating cows producing milk for human consumption.
Do not use in pregnant dry cows and heifers which are intended to produce milk for human consumption within 60 days of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides, which can bind selectively to glutamate-gated chloride ion channels that occur in several invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve and muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels. In addition, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier in normal conditions.

4.3 Pharmacokinetics

Maximum plasma concentration in cattle is reached on average in 5,5 days and in pigs in 3,5 days after administration. The mean elimination half-life is 6 days in cattle and 5,5 days in pigs. Ivermectin is distributed to tissues in the following order: liver > fat > kidney > muscle in cattle and fat > liver > kidney > muscle in pigs. The substance is only partially metabolised. Unmetabolised ivermectin and degradation products are excreted to about 98 % in faeces and 2 % in urine.

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: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton, in order to protect from light.

5.4 Nature and composition of immediate packaging

Vials of polyethylene sealed with bromobutyl stoppers and aluminium overseals in cartons.

Packaging sizes:
Cardboard box with 1 x 50 ml plastic vial.
Cardboard box with 1 x 250 ml plastic vial
Cardboard box with 6 x 250 ml plastic vials
Cardboard box with 1 x 500 ml plastic vial

Not all pack sizes may be marketed.

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.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}

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

2023-10-18

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).