

## SUMMARY OF THE PRODUCT CHARACTERISTICS

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin vet. 10 mg/ml, solution for injection

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active substance(s)

1 ml contains:

Ivermectin 10 mg

#### List of excipients

Glycerol 100 mg

Glycerol formal. to 1 ml

### 3 PHARMACEUTICAL FORM

Solution for injection.

Clear colourless to slightly yellow coloured solution.

### 4 PHARMACOLOGICAL PROPERTIES

Endectocides QP54AA01

#### 4.1 Pharmacodynamic properties

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.

#### 4.2 Pharmacokinetic properties

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 CLINICAL PARTICULARS

### 5.0 Target species

Cattle, reindeer and pigs.

### 5.1 Indications for use, specifying the target species

Bimectin vet. Injection is indicated for treatment of the following parasites of cattle, reindeer and pigs:

#### **Cattle:**

##### **Gastro-intestinal roundworms** (adult and fourth stage larvae, L<sub>4</sub>)

*Ostertagia ostertagi*. (including inhibited L<sub>4</sub>)

*Ostertagia lyrata*

*Haemonochus placei*

*Trichostrongylus axei*

*Trichostrongylus colubriformis* (L<sub>4</sub>)

*Cooperia* spp.

*Oesophagostomum radiatum*

*Nematodirus spathiger* (adult)

##### **Lungworms** (adult and fourth stage larvae, L<sub>4</sub>)

*Dictyocaulus viviparus*.

##### **Warbles** (larval stages)

*Hypoderma bovis*

*Hypoderma lineatum*.

##### **Mange mites**

*Sarcoptes scabiei* var. *bovis*

*Psoroptes bovis*

##### **Lice**

*Linognathus vituli*

*Haematopinus eurysternus*

##### **Reindeer**

Larval stages of *Hypoderma tarandi*.

#### **Pigs:**

##### **Gastro-intestinal roundworms** (adult and fourth stage larvae, L<sub>4</sub>)

*Ascaris suum*

*Hyostromylus rubidus*

*Oesophagostomum* spp.

*Strongyloides ransomi* (adult)

##### **Lungworms**

*Metastrongylus* spp. (adult)

**Mange mites**

*Sarcoptes scabiei* var. *suis*

**Lice**

*Haematopinus suis*

**5.2 Contraindications**

Should not be given to animals with known hypersensitivity to ivermectin.

**5.3 Undesirable effects**

Local reaction at the injection site may occur.

**5.4 Special precaution(s) for use**

Avermectins/Melbecycins 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).

**5.5 Pregnancy and lactation**

Bimectin vet. Injection can be administered to beef cows and pigs at any stage of pregnancy or lactation. Bimectin vet. Injection 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.

**5.6 Interaction with other veterinary medicinal products and other forms of interaction**

None known.

**5.7 Posology and method of administration**

Bimectin vet. Injection should be given by subcutaneous injection.

*Cattle and reindeer:* 1 ml of Bimectin vet. Injection per 50 kg bodyweight, corresponding to 0.2 mg ivermectin per kg bodyweight.

*Pigs:* 1 ml of Bimectin vet. Injection per 33 kg bodyweight, corresponding to 0.3 mg ivermectin per kg bodyweight.

**5.8 Overdose**

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

**5.9 Special warnings for each 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.

**5.10 Withdrawal period**

*Slaughter:* Cattle 35 days, reindeer and pigs 28 days.

Lactating cows producing milk for human consumption should not be treated. Dry cows and heifers should not be treated within 60 days prior to calving.

**5.11 Special precautions to be taken by the person administering the veterinary medicinal product to animals.**

None specific.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 Incompatibilities (major)**

Due to lack of incompatibility studies, this veterinary medicinal drug should not be mixed with other veterinary medicinal drugs.

**6.2 Shelf life**

2 years.

After first opening, the product should be used within 28 days.

**6.3 Special precautions for storage**

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

**6.4 Nature and contents of container**

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

Packaging sizes:           1 x 50 ml  
                                  1 x 250 ml  
                                  1 x 6 x 250 ml  
                                  1 x 500 ml

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

Free ivermectin is very toxic to fish and other water-borne organisms. Residual drug must be handed in to the pharmacy for destruction.

**7 PROHIBITION OF SALE, SUPPLY AND/OR USE**

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**8 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Bimeda (Cross Vetpharm Group Ltd)  
Broomhill Road  
Tallaght  
Dublin 24  
Ireland

**9 NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

15652

**10 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

2001-10-18

**11      DATE OF REVISION OF THE TEXT**

2003-06-18