Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcimec 10 mg/ml solution for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Ivermectin 1.0 % w/v (10 mg/ml)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.
The product can be given to all ages of animals including piglets.

4.2 Indications for use, specifying the target species

The product is indicated for the effective treatment and control of the following harmful parasites of pigs:

Gastrointestinal roundworms: (Adults and fourth stage larvae):

Ascaris suum
Hyostrongylus rubidus

Oesophagostomum spp.
*Strongyloides ransomi (*adults and somatic larval stages)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredient.
Do not administer by the intravenous or intramuscular route.
Do not use in cats and dogs as severe adverse reactions may occur.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The product has been formulated specifically for use in pigs only. It should not be administered to other species as severe adverse reactions may occur. 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.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. Assess bodyweight as accurately as possible before calculating the dosage.

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

Take care to avoid self-administration: the product may cause local irritation and/or pain at the site of injection.
Do not smoke or eat while handling the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient pain reactions may be seen in some pigs following subcutaneous injection at injection site. All these reactions disappeared without treatment

4.7 Use during pregnancy, lactation or lay

The product can be used in breeding sows and boars and will not affect fertility.
Do not administer the product during the first 40 days of pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

The product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

4.9 Amounts to be administered and administration route

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended. If using a single-dose hypodermic syringe, use a separate sterile needle to withdraw the product from the container.

In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

Young Pigs:
In young pigs, especially those below 16 kg for which less than 0.5 ml the product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

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

A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

4.11 Withdrawal period(s)

Meat: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antiparasitic Products, insecticides and repellents, Endectocides
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin belongs to the avermectin group. Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in 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 or 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 (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

At a dose level of 0.3 mg ivermectin per kg bodyweight, a mean Cmax of 6.94 ng/ml was reached at a mean Tmax of 86.75 hours, and the mean elimination half life was 133.56 hours. Biliary excretion, followed by elimination in faeces is probably the major route f Ivermectin excretion in pigs. While the major single component excreted was unaltered drug, the major metabolite in swine are 3' -O-desmethyl-H_2B_{1a} and 3' -O-desmethyl-$H_2B_{1b.}$

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Glycerol Formal

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Multidose high density polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and plain aluminium overseals, containing a clear, colourless sterile solution.
Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements. The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/052/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 August 2006
Date of last renewal: 02 March 2007

10 DATE OF REVISION OF THE TEXT

June 2019