Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Injection for Pigs 1% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ivermectin 1.0% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless, slightly viscous, non-aqueous sterile solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

In swine: treatment of the infections by the following parasites:

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

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 substance.
Do not administer by the intravenous or intramuscular route.
Do not use in cats or dogs as severe adverse reactions may occur.

4.4 Special warnings for each target species

Details provided above apply. See also points 4.3, 4.5 and 4.7.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals

Parasite resistance to any particular class of anthelmintic may develop following repeated use of an anthelminic of that class.

Avermectins 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 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. Do not administer the product during the first 40 days of pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Avoid underdosing. Assess bodyweight as accurately as possible before calculating the dosage.

For single treatment only. The product should be injected subcutaneously.

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.

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 of 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.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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 and offal: 32 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QP54AA01. Pharmacotherapeutic Group: Endectocide.

5.1 Pharmacodynamic properties

Ivermectin is a member of the avermectin group. Ivermectin is a member of the macrocyclic lactone class of endectocides. 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 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, 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 0.3mg ivermectin per kg bodyweight, a mean Cmax of 6.94 ng/ml was reached at a mean Tmax of 86.75 hours. Biliary excretion, followed by elimination in faeces is probably the major route of 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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 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.

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 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 veterinary product or waste material derived from the product should be disposed of in accordance with local 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
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/063/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 October 2004
Date of last renewal: 01 June 2010

10 DATE OF REVISION OF THE TEXT

June 2019