Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Medimec Injection 10 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:
Ivermectin 10 mg/ml

Excipients:
For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Pigs.

4.2 Indications for use, specifying the target species

Medimec Injection is indicated for the treatment of the following parasites of cattle and pigs:
Cattle:

Gastro-intestinal roundworms (adult and fourth stage larvae):
Ostertagia spp (including inhibited *O. ostertagi*),
Haemonchus placei,
Trichostrongylus axei,
Trichostrongylus colubriformis,
Cooperia spp,
Oesophagostomum radiatum,
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult),
N. spathiger (adult)
Toxocara vitulorum,
Trichuris spp. (adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.

Eye worms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis and *H. lineatum*.

Mange mites:
Psoroptes communis var. bovis,
Sarcoptes scabiei var. *bovis*.

Sucking lice:
Linognathus vituli,
Haematopinus eurysternus

May also be used as an aid in the reduction of infestation of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Pigs:

Gastrointestinal worms (adult and fourth stage larvae):
Ascaris suum,
Hyostrongylus rubidus,
Oesophagostomum spp,
Strongyloides ransomi (adult stage)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient. Do not administer by the intravenous or intramuscular route.

4.4 Special warnings for each target species

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.

Resistance to ivermectin has been reported in *Ostertagia ostertagi* in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of the helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Avermectins may not be well tolerated in non-target species. Cases of intolerance with fatal results are reported in dogs especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

In Cattle:
The volume administered per injection site should not exceed 10ml.
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

In Pigs:
The volume administered per injection site should not exceed 5ml.

Special Precautions to be taken by the Person Administering the 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)

Cattle
Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment.

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

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy in cows. Do not use in non lactating dairy cows, including pregnant heifers within 60 days of calving. In pigs, the product can be used in breeding sows and boars. Do not administer the product in pigs during the first 40 days of pregnancy. The fertility of males is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interactions

Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

4.9 Amounts to be administered and administration route

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle, and 33 kg of bodyweight of pigs. The injection may be given with any standard automatic on single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested.

Cattle
Medimec Injection should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle. This is equivalent to 1 ml per 50 kg bodyweight.

Pigs
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 Medimec Injection is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. Accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

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

Cattle
Single dose of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
Pigs
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.

Cattle and Pigs
No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species, cattle and pigs.

4.11 Withdrawal period(s)

Cattle
Meat and offal: 49 days
Do not use in lactating dairy cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers within 60 days of calving.

Pigs
Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Endectocides
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides. Compounds of this 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

Maximum plasma concentration
Cattle
At a dose level of 0.2 mg ivermectin per kg a Cmax of 30 ng/ml is reached at a Tmax of 131 hours with an elimination half-life of 5.9 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Pigs
At a dose level of 0.3 mg ivermectin per kg bodyweight, a mean C_{max} of 6.94 ng/ml was reached at a mean T_{max} of 86.75 hours, and the mean elimination half life was 133.56 hours.

Excretion: length of time and route
Cattle
Only about 1 - 2% is excreted in the urine, the remainder is excreted in the faeces approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products.

Pigs
Biliary excretion is also the major route of ivermectin excretion in pigs.

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 should not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged: 3 years.
Shelf-life after first opening the immediate packageing: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Multidose polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and aluminium overseals. 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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/156/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 February 2005
Date of last renewal: 27 July 2010

10 DATE OF REVISION OF THE TEXT

November 2018