Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sumex 1% w/v 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 to slightly yellow solution

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

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

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

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

4.3 Contraindications

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

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 dose.
The product has been formulated specifically for use in pigs only. Do not use in cats and dogs. 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 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 the 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. As the safety of ivermectin injection has not been demonstrated in sows during early pregnancy, the product should not be given to sows in the 1st trimester of pregnancy (Day 1 - 40).

4.8 Interaction with other medicinal products and other forms of interactions

The product can be used concurrently, without adverse effects, with clostridial vaccine, given at separate injection sites

4.9 Amounts to be administered and administration route

The product is administered as a single injection. Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs. Massage the injection site after administration of the product. Injection of wet or dirty animals is not recommended.

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 of the product is indicated, dosing accurately 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

There is no specific antidote.
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: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Ivermectin is a member of the avermectin group. Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. 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

At a dose level of 0.3 mg ivermectin per kg bodyweight, a Cmax of 6.9 ng/ml was reached at a Tmax of 3.6 days, and the elimination half life was 5.5 days.

Billary excretion, followed by elimination in faeces is the major route of ivermectin excretion in pigs. While the major single component excreted was unaltered drug, the main metabolites 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 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 precautions.

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

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/151/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2002
Date of last renewal: 10th October 2007

10 DATE OF REVISION OF THE TEXT

November 2018