Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sumex 1 %w/v solution for injection for cattle

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

Cattle (Beef and non lactating cattle)

4.2 Indications for use, specifying the target species

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

Gastro-intestinal roundworms:
Ostertagia spp (including inhibited *O. ostertagi (adult and L4*)),
Haemonchus placei (adult and L4),
Trichostrongylus spp (adult and L4),
Cooperia spp *(adult and L4*),
Nematodirus spp (adult),

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Warbles (parasitic stages):
Hypoderma spp

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

Sucking lice:
Linognathus vituli,
Haematopinus eurysternus

Persistent activity

Treatment at the recommended dose rate controls re-infection with *Haemonchusplacei* and *Cooperia spp.* acquired up to 14 days after treatment, *Ostertagia ostertagi* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain maximum benefit from the persistent activity of the product for grazing animals it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastroenteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture.
Treated calves should always be monitored according to good husbandry practices.

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.
Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Administer the product only subcutaneously because intramuscular administration causes persistent drug residues at the site of injection.
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.
The product has been formulated specifically for use in cattle 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 anthelmint 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.

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)

Transitory discomfort and a low incidence of soft tissue swelling have been observed at the injection site in some cattle following subcutaneous administration.These reactions have disappeared without treatment within 28 days.

4.7 Use during pregnancy, lactation or lay

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

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 50 kg of bodyweight of cattle. Massage the injection site after administration of the product. Injection of wet or dirty animals is not recommended.

The product 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. The volume administered per injection site should not exceed 10 ml.

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

There is no specific antidote.
Single dose of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

4.11 Withdrawal period(s)

Meat and offal: 49 days
Milk: Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

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 0.2 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 distributed mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.
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. The major metabolite in cattle is 24-hydroxymethyl H2B1a and its fatty acid esters. Almost all of the metabolites of

Ivermectin are more polar than the parent compound and no single minor metabolite accounts for more than 4% of total metabolites.

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)

VPA10987/150/001

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