Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sumex 5 mg/ml Pour on Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Ingredient
Ivermectin 5.0 mg

Excipients
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution.
A clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of the following species of gastrointestinal roundworms, lungworms, warbles, mites and lice:

Gastro-intestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited O ostertagi)
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp
Oesophagostomum radiatum
Strongyloides papillosus (adult only)
Trichuris spp (adult only)

Lungworms(adult and fourth stage larvae):
Dictyocaulus viviparus

Eye worms (adult):
Thelazia spp

Warbles(parasitic stages):
Hypoderma bovis
Hypoderma lineatum

Mites:
Chorioptes bovis (reduction of infestation)
Sarcoptes scabiei var bovis.

Sucking lice:
Linognathus vituli,
Haematopinus eurysternus

Biting Lice:
Damalinia bovis

The product given at the recommended dosage of 500 micrograms/kg bodyweight, has persistent activity against Trichostrongylus axei and Cooperia spp acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against Ostertagia ostertagi and Oesophagostomum radiatum acquired during the first 21 days after treatment and Dictyocaulus viviparus (lungworm) acquired during the first 28 days after treatment. It also has a persistent activity on horn flies (Haematobia irritans) for 28 days after treatment, partial efficacy may last for up to 35 days post application. Occasionally variable activity may be observed against Haemonchus placei (L4), Cooperia spp, Trichostrongylus axei and Trichostrongylus colubriformis.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in lactating animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days prior to calving.
Do not use in species other than cattle as severe adverse reactions, including fatalities in dogs, may occur.

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

4.5 Special precautions for use

Special precautions for use in animals

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.
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 the period of warble fly activity and before the larvae reach their resting site.Do not treat cattle when their hair or hide is wet. Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment. Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.
The influence of extreme climatic conditions on persistent activity of the product is unknown.

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

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. Use only in well-ventilated areas or outdoors. Highly flammable. Keep away from heat, spark, open flame or other source of ignition. Do not eat, drink or smoke whilst handling the product.

As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occasionally slight irritation at the application site may occur. However, usually these irritations rapidly disappear without treatment.

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.
The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For pour-on use.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 500 micrograms/kg bodyweight).
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
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.

The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead. The product should be used with appropriate dosing equipment. The interval between 2 treatments should be at least 28 days.

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

No sign of toxicity appeared up to 1.5 mg/kg (3 times the recommended dose rate). No antidote has been identified. The signs of overdose can be trembling, convulsions and coma. In case of overdose symptomatic treatment should be given.

4.11 Withdrawal period(s)

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antiparasitic Products, insecticides and repellents, Endectocides
ATCvet code: QP54AA01. Ivermectin is a member of the avermectin group.

5.1 Pharmacodynamic properties

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 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

After topical administration of the product at the recommended dose of 500 microgram per kg bodyweight, plasma concentrations increased to an average plateau of 12-16 ng/ml between 36-144 hours post treatment (T_{max} is 3.7 days) with a Cmax of 16.89 ng/ml. After day 6 the ivermectin levels gradually decreased to an average of less than 2 ng/ml at 28 days. The concentrations mentioned relate to the main component of ivermectin, 22,23-dihydroavermectin B1a. The mean AUC for ivermectin is about 4157 ng/ml/hr with an elimination half life of 6.4 days.

Liver and fat contain the highest residue levels and muscle the lowest. Ivermectin is mainly excreted in faeces following biliary excretion.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Crodamol CAP
Isopropyl alcohol

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Highly flammable – keep away from heat, sparks, open flame or other sources of ignition. Close container when not in use. Bottles should remain upright during storage. Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene container (flat bottomed flexi packs) with a 38mm tamper evident closure (1L, 2.5L and 5L).
The 1L pack will also have a dial a dose dosing cup.
Pack sizes: 1L, 2.5L, 5L and 6L.
The 6L pack size consists of a 5L and 1L pack combined in one carton.
Or
High density polyethylene squeeze measure pour containers with child resistant closures. Pack sizes: 250ml, 500ml and 1L.
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 FOR FISH AND AQUATIC ORGANISMS. Do not contaminate ponds, waterways or ditches with the product or empty container.

Any unused veterinary medicinal product or waste materials 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)

VPA10987/160/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 January 2007
Date of last renewal: 25 January 2012

10 DATE OF REVISION OF THE TEXT

November 2018