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 substance:
Ivermectin 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Trolamine
Crodamol CAP
Isopropyl alcohol

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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 veterinary medicinal product given at the recommended dosage of 500 µg/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.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in species other than cattle as severe adverse reactions, including fatalities in dogs, may occur.

3.4 Special warnings

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 veterinary medicinal 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.

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 veterinary medicinal 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the veterinary medicinal product at the end of the period of warble fly activity and before the larvae reach their resting site.

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

The veterinary medicinal product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:
The influence of extreme climatic conditions on persistent activity of the veterinary medicinal product is unknown.

Other precautions:
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.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Application site irritation[1]

[1]Slight. Usually rapidly disappears without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
The veterinary medicinal product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 500 µg/kg bodyweight).
To ensure a correct dosage, 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 veterinary medicinal product should be used with appropriate dosing equipment. The interval between 2 treatments should be at least 28 days.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QP54AA01.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

After topical administration of the veterinary medicinal 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 C_{max} 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Keep the container tightly closed when not in use. Store the bottles upright in the outer carton. Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene container (flat bottomed flexi packs) with a 38 mm tamper evident closure (1 L, 2.5 L and 5 L).
The 1 L pack will also have a dial a dose dosing cup.
Pack sizes: 1 L, 2.5 L, 5 L and 6 L.
The 6 L pack size consists of a 5 L and 1 L pack combined in one carton.
Or
High density polyethylene squeeze measure pour containers with child resistant closures.
Pack sizes: 250 ml, 500 ml and 1 L.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/160/001

8. DATE OF FIRST AUTHORISATION

19/01/2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

23/10/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).