

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Topimec Plus 10/100 mg/ml Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains:

Active substances:

Ivermectin 10 mg

Clorsulon 100 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

A clear colourless to pale yellow coloured sterile non-aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of mixed infestation of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non-lactating dairy cattle.

Gastrointestinal roundworms (adult and fourth-stage larvae):

Ostertagia ostertagi (including inhibited larval stages)

O. lyrata

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Cooperia oncophora

C. punctata

C. pectinata

Bunostomum phlebotomum

Oesophagostomum radiatum

Strongyloides papillosus (adult)

Nematodirus spathiger (adult)

Nematodirus helvetianus (adult)

Trichuris spp (adult)

Lungworms (adult and fourth-stage larvae)

Dictyocaulus viviparus

Liver fluke (adult):

Fasciola hepatica

Eye worms (adult):

Thelazia spp

Warbles (parasitic stages):

Hypoderma bovis

H. lineatum

Mange mites:

Psoroptes bovis

Sarcoptes scabiei var. *bovis*

Sucking lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus.

The product may also be used as an aid in the treatment of biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity

The product given at the recommended dosage of 1 ml/50kg body weight controls re-infection with *Haemonchus placei*, *Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

4.3 Contraindications

Do not use intramuscularly or intravenously.

The product is a low volume product authorised for use in cattle. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur (especially Collies, Old English Sheepdogs and related breeds or crosses). Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.

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 (if any).

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

4.5 Special precautions for use

i) Special precautions for use in animals

This product does not contain any antimicrobial preservative. Swab septum before removing each dose.

To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting sites: seek professional advice on the correct timing of treatment.

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

Do not smoke, eat or drink whilst handling the product. Wash hands after use. Direct contact with the skin should be avoided. Wear gloves and glasses when handling the veterinary medicinal product. Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice and show the label to the doctor.

iii) Other precautions

The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeated treatments on a pasture within a season should only be given on the advice of a veterinarian.

4.6 Adverse reactions (frequency and seriousness)

Target species: Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	*Injection site swelling. *Transient injection site pain.
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*These reactions disappeared 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 also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Can be used in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Subcutaneous use

Dosage and duration of treatment

A single dose of 1ml per 50kg body weight, i.e. 200µg ivermectin and 2mg clorsulon per kg body weight.

Method of administration

The product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder.

Divide doses greater than 10ml between two injection sites. A sterile 17 gauge ½ inch (15-20mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.

Different injection sites should be used for other parenteral products administered concurrently. When using the 500ml pack size use only automatic syringe equipment. For the 50ml pack size, use of a multidose syringe is recommended.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person. To ensure a correct dosage, 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, to avoid under- or over-dosing, they should be grouped according to their body weight and dosed accordingly.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

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

A dose of 25ml product per 50kg body weight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

4.11 Withdrawal period(s)

Meat and offal: 66 days

Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: *Endectocides, macrocyclic lactones, avermectins, ivermectin – combinations*

ATC Vet Code: QP54AA51

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides and has a unique mode of action. It has broad and potent antiparasitic activity. It binds 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 hyperpolarisation 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-amino-butyric 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, that the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Clorsulon is a sulphonamide. Clorsulon is rapidly absorbed in the blood stream. It is bound to the erythrocytes and plasma which are ingested by the fluke. Clorsulon inhibits the glycolytic enzymes in the fluke and deprives it of its main source of metabolic energy.

5.2 Pharmacokinetic particulars

After subcutaneous administration of 2mg clorsulon and 0.2mg ivermectin per kg body weight, the plasma profile demonstrated the slow, steady absorption of ivermectin which reached a maximum plasma concentration at a median time of 1.50 days. In contrast, clorsulon appeared rapidly absorbed with maximum plasma at a median time of 0.25 days. The terminal half life for the two active ingredients were determined as follows: 3.79 days for ivermectin and 3.58 days for Clorsulon.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal
Propylene glycol
Monoethanolamine (for pH adjustment)

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 temperature storage conditions.

Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Container material: High density polyethylene
Container closure: Siliconised grey bromobutyl rubber stopper
Container colour: Natural
Container volume: 50ml, 250ml or 500ml
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 the product or used container.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd
7 Rodney Street
Liverpool
L1 9HZ

8. MARKETING AUTHORISATION NUMBER

Vm 11990/5000

9. DATE OF FIRST AUTHORISATION

21 January 2011

10. DATE OF REVISION OF THE TEXT

December 2022