1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Topimec Super solution for injection (IE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin 10 mg
Clorsulon 100 mg

Excipients:

Qualitative composition of excipients and other constituents.
Glycerol formal
Propylene glycol
Disodium EDTA
N-propyl gallate
Thipdipropionic acid
Monoethanolamine (for pH adjustment)

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and non-lactating dairy cattle).

3.2 Indications for use for each target species

For the treatment of mixed infestations of the following parasite species:

Gastrointestinal Roundworms (adult and fourth-stage larvae):
*Ostertagia spp. (*including inhibited *O. ostertagi)*
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp.
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult only)
Nematodirus helvetianus (adult only)
Nematodirus spathiger (adult only)

Toxocara vitulorum
Trichuris spp. (adult only)

Lungworm (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 eursternus
Solenopotes capillatus

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

Persistent Activity
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the veterinary medicinal product at the recommended dose rate can control re-infection with *Haemonchus placei* and *Cooperia* spp., acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocalus vivparus* acquired up to 28 days after treatment.

3.3 Contraindications

Do not use intramuscularly or intravenously.
This veterinary medicinal product is registered for use in cattle only. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur (especially Collies, Old English Sheepdogs and related breeds and crosses).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 bodyweight, 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

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

Do not eat, drink or smoke while handling the veterinary medicinal product.
Wash hands after use.
Direct contact with the skin should be avoided. In the event of accidental skin contact, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water.
Take care to avoid self-administration; the veterinary medicinal product may cause local irritation and/or pain at the site of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

The veterinary medicinal 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 treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

Other precautions:
Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the avaiable data):	Injection site pain[1] Injection site swelling.[2]

[1]Transitory discomfort.
[2] Soft- tissue reaction, resolves over time 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 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:
The veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

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

Subcutaneous use.

Dosage and duration of treatment:

The veterinary medicinal product should be given at the recommended dosage level of 1 ml/50 kg bodyweight (based on a dosage level of 200 µg ivermectin plus 2 mg clorsulon per kg bodyweight).

Method of administration:
The veterinary medicinal product should be administered only by subcutaneous injection under the loose skin in front of, or behind, the shoulder. Divide doses greater than 10 ml between two injection sites.
A sterile 17 gauge ½-inch (15-20 mm) needle is recommended.
When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.
When the temperature of the veterinary medicinal product is below 5 ºC, difficulty in administration may be encountered due to increased viscosity. Warming the veterinary medicinal product and injection equipment to about 15 ºC will greatly increase the ease with which the product can be injected. Different injection sites should be used for other parenteral products.

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 bodyweight and dosed accordingly.

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

The administration of 5 ml per 50 kg bodyweight (5 x the recommended dose rate) resulted in injection site lesions (including swelling, sensitivity, oedema and inflammation).
No other drug-related adverse reactions are expected.

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: 66 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP54AA51

4.2 Pharmacodynamics

Ivermectin
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.

Clorsulon
Clorsulon is a sulfonamide. Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola* spp. Adult *Fasciola* spp. are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

4.3 Pharmacokinetics

After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, maximum plasma concentrations of ivermectin (C_{max}: 65.80 ng/ml) were achieved 1-2 days after treatment and maximum plasma concentrations of clorsulon (C_{max}: 2.58 µg/ml) were achieved approximately 8 hours after treatment. The terminal half-life for the two active ingredients were determined as follows: ivermectin approximately 3.79 days and clorsulon approximately 3.58 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Container material: High density polyethylene.
Container closure: Siliconised grey bromobutyl rubber stopper.
Container volume: 50, 250 or 500 ml.

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 this veterinary medicinal product is 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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/0099/001

8. DATE OF FIRST AUTHORISATION

14/10/2011

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

07/08/2026

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).