

## **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

#### **Excipients:**

<b>Qualitative composition of excipients</b>
Glycerol formal
Propylene glycol
Monoethanolamine (for pH adjustment)

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

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Cattle

#### **3.2 Indications for use for each 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.

### **3.3 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 cases of hypersensitivity to the active substances 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 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.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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.

#### 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 immediately and show the package leaflet or the label to the physician.

#### Special precautions for the protection of the environment:

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.

### 3.6 Adverse events

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.

### **3.7 Use during pregnancy, lactation or lay**

#### Pregnancy and lactation:

Can be used during pregnancy and lactation.

Can be used in breeding animals.

### **3.8 Interactions with other medicinal products and other forms of interaction**

None known.

### **3.9 Administration routes and dosage**

Subcutaneous use

#### *Dosage and duration of treatment*

A single dose of 1 ml per 50 kg body weight, i.e. 200 µg ivermectin and 2 mg 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 (15-20 mm) 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 500 ml pack size use only automatic syringe equipment. For the 50 ml 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.

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

A dose of 25 ml 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.

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

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP54AA51

### **4.2 Pharmacodynamics**

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, which 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.

### **4.3 Pharmacokinetics**

After subcutaneous administration of 2 mg clorsulon and 0.2 mg 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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must 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**

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.

### **5.4 Nature and composition of immediate packaging**

One HDPE bottle in a cardboard box.

Container material: High density polyethylene  
Container closure: Siliconised grey bromobutyl rubber stopper  
Container colour: Natural  
Container volume: 50 ml, 250 ml 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. The veterinary medicinal product should not enter water courses as Ivermectin and Clorsulon may be 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 Animal Health Ltd  
7 Rodney Street  
Liverpool  
L1 9HZ

**7. MARKETING AUTHORISATION NUMBER**

Vm 11990/3000

**8. DATE OF FIRST AUTHORISATION**

21 January 2011

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

December 2022

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

<To be completed nationally>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

Approved 16 December 2022

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.