A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{PRINTED CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains:
Ivermectin 10 mg
Clorsulon 100 mg

3. PACKAGE SIZE

50 ml,
250 ml or
500 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

For products not subject to veterinary prescription:

For the treatment of mixed infestations of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non-lactating dairy cattle.

6. ROUTES OF ADMINISTRATION

SUBCUTANEOUS USE

7. 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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached used by…

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/3045

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{PACK LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains:
Ivermectin 10 mg
Clorsulon 100 mg

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use

Read the package leaflet before use.

5. 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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached use by.....

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

1 ml of solution contains:

Active substances:
Ivermectin 10 mg
Clorsulon 100 mg

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

3. Target species

Cattle

4. Indications for use

For the treatment of mixed infestations of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non-lactating dairy cattle.

Ivermectin Clorsulon 10/100 mg/ml Solution for Injection for Cattle treats:

PARASITE	Adult	L4	Inhibited L4
Gastrointestinal roundworms			
Ostertagia ostertagi	+	+	+
Ostertagia lyrata	+	+	
Haemonchus placei	+	+	
Trichostrongylus axei	+	+	
Trichostrongylus colubriformis	+	+	
Cooperia oncophora	+	+	
Cooperia punctata	+	+	
Cooperia pectinata	+	+	
Bunostomum phlebotomum	+	+	
Oesophagostomum radiatum	+	+	
Strongyloides papillosus	+		
Nematodirus helvetianus	+		
Nematodirus spathiger	+		
Trichuris spp	+		

PARASITE	Adult	L4	Inhibited L4
Lungworms			
Dictyocaulus viviparus	+	+	
Eye worms			
Thelazia spp.	+		

PARASITE	Adult	Immature
Liver fluke		
Fasciola heptica	+	
Warbles (parasitic stages)		
Hypoderma bovis		+
H. lineatum		+
Mange mites		
Psoroptes bovis	+	+
Sarcoptes scabiei var bovis	+	+
Sucking lice		
Linognathus vituli	+	+
Haematopinus eurysternus	+	+
Solenopotes capillatus	+	+

PERSISTENT ACTIVITY

Ivermectin Clorsulon 10/100 mg/ml Solution for Injection for Cattle given at the recommended dosage of 1 ml per 50 kg body weight controls re-infection with the following nematodes up to the duration shown:

PARASITE	NO. OF DAYS AFTER TREATMENT
Barber's pole worm – *Haemonchus placei*	14
Small intestinal worm – *Cooperia spp*	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm – *Ostertagia ostertagi*	21
Nodular worm – *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparus*	28

Ivermectin Clorsulon 10/100 mg/ml Solution for Injection for Cattle 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.

5. 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.

6. Special warnings

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.

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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.
Can be used in breeding animals.

Overdose:
A dose of 25 ml product per 50 kg 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.

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

7. Adverse events

Target species: Cattle.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	*Injection site swelling *Transient injection site pain

*These reactions disappeared without treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder / <the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Subcutaneous use

The recommended dose rate is 1 ml per 50 kg body weight by subcutaneous injection. This dose delivers 200 µg ivermectin and 2 mg clorsulon per kg body weight.

For example:

Body weight (kg)	**Dose volume (ml)**	**Doses per 50 ml pack**	**Doses per 250 ml pack**	**Doses per 500 ml pack**
Up to 50	1	50	250	500
51-100	2	25	125	250
101-150	3	16	83	166
151-200	4	12	62	125
201-250	5	10	50	100
251-300	6	8	40	83

Over 300 kg give 1 ml per 50 kg body weight.

9. Advice on correct administration

Inject only by the subcutaneous route under the loose skin in front of or behind the shoulder.

Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications. 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 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 suitably qualified person. To ensure a correct dosage, body weight should be determined as accurately as possible.

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. Accuracy of the dosing device should be checked.

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

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

<To be completed nationally>

14. Marketing authorisation numbers and pack sizes

Package quantities: 50 ml, 250 ml and 500 ml containers
Not all pack sizes may be marketed

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

and contact details to report suspected adverse reactions:

<To be completed nationally>

Local representatives <and contact details to report suspected adverse reactions:
<To be completed nationally>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

MODE OF ACTION

Ivermectin acts on the nervous system of nematode and arthropod parasites. It first paralyses, then kills them. At therapeutic usage rates it has no effect on the nervous system of cattle.
Clorsulon acts on enzymes involved in energy generation in liver fluke. At therapeutic usage rates it has no effect on the equivalent systems of cattle.
At the recommended usage rate Ivermectin Clorsulon 10/100 mg/ml Solution for Injection for Cattle has no adverse effects on breeding performance of cattle. At therapeutic usage rates it has no effect on the nervous system of cattle.

Gavin Hall
Approved: 26 September 2025