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 AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

50ml,
250ml or
500ml

4. TARGET SPECIES

Cattle

5. INDICATION(S)

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
Read the package leaflet before 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 use 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.

POM-VPS

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health, 7 Rodney Street, Liverpool L1 9HZ United Kingdom

14. MARKETING AUTHORISATION NUMBERS

Vm 11990/5000

15. BATCH NUMBER

BN:

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

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 AND OTHER SUBSTANCES

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

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous injection
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health, 7 Rodney Street, Liverpool L1 9HZ United Kingdom

9. BATCH NUMBER

BN:

10. PACKAGE SIZE

50ml,
250ml or
500ml

11. INDICATION(S)

Read the package leaflet before use.

12. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-VPS

15. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/5000

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:
Ivermectin 10mg
Clorsulon 100mg

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 10/100mg/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 10/100mg/ml Solution for Injection for Cattle given at the recommended dosage of 1ml per 50kg 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 10/100mg/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.
Ivermectin Clorsulon 10/100mg/ml Solution for Injection for Cattle is a low volume product authorised for use in cattle. It must not be used 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 WARNING(S)

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 in 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, ROUTE(S) AND METHOD OF ADMINISTRATION

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

Body weight (kg)	**Dose volume (ml)**	**Doses per 50ml pack**	**Doses per 250ml pack**	**Doses per 500ml 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 300kg give 1ml per 50kg body weight.

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.

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.

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.
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 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.

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.
Once opened use within 28 days.
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.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Medicines should not be disposed of via wastewater. 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.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Legal Category: POM-VPS To be supplied only on veterinary prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 11990/5000

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

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

December 2022

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

16. CONTACT DETAILS

Marketing authorisation holder
Chanelle Animal Health, 7 Rodney Street, Liverpool L1 9HZ, United Kingdom

Manufacturer for the batch release
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

17. OTHER INFORMATION

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 10/100mg/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.
Pharmacotherapeutic group: Endectocides, ivermectin, combinations.

Approved 16 December 2022