

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton (1L, 2.5L, 3L & 5L)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epromec 5 mg/ml Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5 mg/ml

3. PACKAGE SIZE

1 L, 2.5 L, 3 L & 5 L

4. TARGET SPECIES

Cattle (beef and dairy cattle)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and Offal: 15 days.

Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

Once opened use by.....

9. SPECIAL STORAGE PRECAUTIONS

For Squeeze pour containers (1L): Keep the container in the outer container in order to protect from light.

For Flexi-pack containers (2.5 L, 3 L and 5L): 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.

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/4059

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {High density polyethylene container (1L, 2.5L, 3L &5L)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epromec 5 mg/ml Pour-on Solution for beef and dairy cattle

2. COMPOSITION

Each ml contains:

Active substance:

Eprinomectin 5.0 mg

Excipients:

Butylated hydroxytoluene (E321) 10.0 mg

Clear solution.

3. PACKAGE SIZE

1 L, 2.5 L, 3 L & 5 L

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS FOR USE

Indications for use

Treatment of infestations by the following internal and external parasites sensitive to eprinomectin:

Gastrointestinal roundworms (adults and fourth-stage larvae)

Ostertagia spp.

Ostertagia lyrata (adults only)

Ostertagia ostertagi (including inhibited L4)

Cooperia spp. (including inhibited L4)

Cooperia oncophora

Cooperia pectinata

Cooperia punctata

Cooperia surnabada

Haemonchus placei

Trichostrongylus spp.

Trichostrongylus axei

Trichostrongylus colubriformis

Bunostomum phlebotomum

Nematodirus helvetianus

Oesophagostomum spp. (adults only)

Oesophagostomum radiatum

Trichuris spp. (adults only)

Lungworms

Dictyocaulus viviparus (adults and L4)

Warbles (parasitic stages)

Hypoderma bovis

Hypoderma lineatum

Mange Mites

Chorioptes bovis

Sarcoptes scabiei var. *bovis*

Lice

Damalinia (Bovicola) bovis (biting lice)

Linognathus vituli (sucking lice)

Haematopinus eurysternus (sucking lice)

Solenopotes capillatus (sucking lice)

Horn flies

Haematobia irritans

Prevention of reinfestations:

The veterinary medicinal product protects the animals against reinfestations with:

- *Nematodirus helvetianus* for 14 days.
- *Trichostrongylus axei* and *Haemonchus placei* for 21 days.
- *Dictyocaulus viviparus*, *Cooperia oncophora*, *Cooperia punctata*, *Cooperia surnabada*, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

6. CONTRAINDICATIONS

Contraindications

The veterinary medicinal product is formulated only for topical application for beef and dairy cattle, including lactating dairy cattle.

Do not use in other animal species.

Do not administer orally or by injection.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

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 bodyweight, misadministration of the veterinary medicinal 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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported within the EU. However, resistance to other macrocyclic lactones has been reported in parasite species in cattle within the EU. Therefore, use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

If there is a risk for re- infection, the advice of a veterinarian should be sought regarding the need for and frequency of repeat administration.

For the best results the veterinary medicinal product should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

Special precautions for safe use in the target species:

For external use only.

For effective use, the veterinary medicinal product should not be applied to areas of the backline covered with mud or manure.

The veterinary medicinal product should be applied only on healthy skin.

To avoid adverse reactions due to the death of warble larvae in the oesophagus or backbone, it is recommended to administer the veterinary medicinal product after the end of warble fly activity and before the larvae reach their resting sites in the body; consult a veterinary surgeon regarding the appropriate time for treatment.

Rainfall before or after treatment will not affect the efficacy of the product.

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

This veterinary medicinal product may be irritating to human skin and eyes and may cause hypersensitivity.

Avoid direct contact with the skin or eyes.

Personal protective equipment consisting of rubber gloves and protective clothing should be worn when handling the veterinary medicinal product.

If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush eyes immediately with water.

Do not smoke, eat or drink while handling the veterinary medicinal product.

Wash hands after use. Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.

People with known hypersensitivity to eprinomectin should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Eprinomectin is very toxic to dung fauna and aquatic organisms, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and veterinary medicinal products of the same anthelmintic class) in cattle. The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for three weeks after treatment.

Other precautions:

Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

Pregnancy, lactation and fertility:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects due to the use of eprinomectin at therapeutic doses.

The safety of eprinomectin in cattle has been established during pregnancy and lactation and in reproductive bulls. Can be used during pregnancy and lactation and in reproductive bulls.

Interaction with other medicinal products and other forms of interaction:

Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

Overdose:

No signs of toxicity appeared when 8-week-old calves were treated at up to 5x the therapeutic dose (2.5 mg eprinomectin/kg body weight) 3 times at 7-day intervals. One calf treated once at 10x the therapeutic dose (5 mg/kg body weight) in the tolerance study showed transient dilated pupils. There were no other adverse reactions to the treatment.

No antidote has been identified.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

Cattle (beef and dairy cattle):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Alopecia (hair loss) Pruritus (itching)
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Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 using the contact details on this label, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Dosage:

Administer only by topical application at the dose rate of 1 ml of the veterinary medicinal product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg body weight.

Body weight (kg)	Dose Volume (ml)	Doses per 1 Litre Pack	Doses per 2.5 Litre Pack	Doses per 3 Litre Pack	Doses per 5 Litre Pack
Up to 100	10	100	250	300	500
101 – 150	15	66	166	198	333
151 – 200	20	50	125	150	250
201 – 250	25	40	100	120	200
251 – 300	30	33	83	100	166

Over 300 kg bodyweight, give 5ml per 50 kg bodyweight.

Method of administration:

Pour-on use.

The veterinary medicinal product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

For the 1L presentation:

The bottle is equipped with an integrated dosing system, and has two openings. One opening is connected to the body of the container and the other to the dispensing chamber (dosing system). Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing 5 ml to 25 ml doses). Squeeze the bottle to fill the dispensing chamber with the required volume of veterinary medicinal product.

For the 2.5 L, 3 L and 5 L presentations:

To be used with an appropriate dosing system such as a dosing gun and coupling vented cap. Unscrew the polypropylene cap. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap. After use, coupling vented caps should be removed and replaced by the polypropylene cap.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible and accuracy of the dosing device should be checked.
The veterinary medicinal product should be used with appropriate dosing equipment.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and overdosing.

All the animals belonging to the same group should be treated at the same time.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and Offal: 15 days.

Milk: Zero hours.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

For Squeeze pour containers (1 L): Keep the container in the outer container in order to protect from light.

For Flexi-pack containers (2.5 L, 3 L and 5 L): Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and container after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as eprinomectin is extremely dangerous for fish and other aquatic organisms. Do not contaminate lakes or waterways with the product or used containers.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 08749/4059

Pack sizes: 1 L, 2.5 L, 3 L and 5 L.

Not all pack sizes may be marketed.

16. 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.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland
Telephone: +353 (0)91 841788
E-mail: vetpharmacoviggroup@chanellegroup.ie

18. OTHER INFORMATION

Other information

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

POM-VPS

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 6 months.

Once opened use by.....

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 22 April 2026