

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
CARTON (1 L, 2.5 L, 3 L & 5 L)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Epricert 5 mg/ml Pour-on Solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

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. INDICATION(S)**

**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.

**9. SPECIAL STORAGE CONDITIONS**

*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 NUMBER(S)**

Vm 08749/5056

**15. BATCH NUMBER**

Lot:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET**

**Combined label and package leaflet**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. COMPOSITION**

Each ml contains:

**Active substance:**

Eprinomectin            5 mg

**Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Butylated hydroxytoluene (E321)	10 mg
Propylene glycol dicaprylocaprate	-

A clear solution.

**3. PACK 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**

*Damalinea (Bovicola) bovis* (biting lice)  
*Linognathus vituli* (sucking lice)  
*Haematopinus eurysternus* (sucking lice)  
*Solenopotes capillatus* (sucking lice)

### **Horn flies**

*Haematobia irritans*

### **Prevention of re-infestations:**

The product protects the animals against re-infestations 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**

Do not use in other animal species; avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Do not administer orally or by injection.

Do not use in known 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 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 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 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 product should not be applied to areas of the backline covered with mud or manure.

The 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 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 at any time 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 product may be irritating to human skin and eyes and may cause hypersensitivity.

Avoid direct contact with the skin or eyes.

Wear rubber gloves and protective clothing when applying the 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 the active substance or to any of the excipients 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 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 and lactation:

Laboratory studies (rat, rabbit) have not produced any evidence of a 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 as well as in reproductive bulls.

Major incompatibilities:

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

## 8. ADVERSE REACTIONS

### Adverse events

Cattle (beef and dairy cattle)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia. Application site pruritus.
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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](mailto: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

Pour-on use.

Administer only by topical application at the dose rate of 1 ml of the product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg b.w. The product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

Rainfall before or after treatment will not affect the efficacy of the product.  
All the animals belonging to the same group should be treated at the same time.

<b>Body weight (kg)</b>	<b>Dose Volume (ml)</b>	<b>Doses per 1 Litre Pack</b>	<b>Doses per 2.5 Litre Pack</b>	<b>Doses per 3 Litre Pack</b>	<b>Doses per 5 Litre Pack</b>
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 body weight, give 5 ml per 50 kg body weight.

For the 1 L 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 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 administration of a correct dose, body weight should be determined as accurately as possible and accuracy of the dosing device should be checked. 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.

## **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.

Discard 6 months after first opening.

*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 label after Exp. The expiry date refers to the last day of that month.

## 13. SPECIAL PRECAUTIONS FOR DISPOSAL

### Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as eprinomectin may be 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 NUMBERS AND PACK SIZES

Vm 08749/5056

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

1 L 'Squeeze pour' packs.

2.5 L, 3L and 5 L 'Flexi' packs.

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](http://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,  
Ireland.  
Telephone: +353 (0)91 841788  
vetpharmacoviggroup@chanellegroup.ie

## 18. OTHER INFORMATION

### Other information

POM-VPS

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

## 19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 6 months.

## 21. BATCH NUMBER

Lot {number}

Approved 22 January 2025  
*Gavin Hall*