

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EpriMole 5 mg/ml Pour-on Solution for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per ml:

Active substance:

Eprinomectin: 5 mg

3. PACKAGE SIZE

250mL
1L,
2.5L,
5L

4. TARGET SPECIES

Cattle (dairy, for meat production).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

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

HANDY DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*			
BODYWEIGHT	DOSE VOLUME	NUMBER OF FULL DOSES PER PACK			
		250ml	1 litre	2.5 litre	5 litre
100kg	10ml	25	100	250	500
150kg	15ml	16	66	166	333
200kg	20ml	12	50	125	250
250kg	25ml	10	40	100	200

300kg	30ml	8	33	83	166
350kg	35ml	7	28	71	142
400kg	40ml	6	25	62	125
450kg	45ml	5	22	55	111
500kg	50ml	5	20	50	100
550kg	55ml	4	18	45	90
600kg	60ml	4	16	41	83

* Dose rate 1ml per 10kg bodyweight

7. WITHDRAWAL PERIOD

Withdrawal period:
Meat & offal: 10 days
Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.
Keep the container in the outer carton.
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

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBER

Vm 02000/4340

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EpriMole 5 mg/ml Pour-on Solution for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per ml contains:

Active substance:

Eprinomectin: 5 mg

3. TARGET SPECIES

Cattle (dairy, for meat production)

4. ROUTES OF ADMINISTRATION

Pour-on use

Read the package leaflet before use

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat & offal: 10 days

Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once open use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Keep the container in the outer carton.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EpriMole 5 mg/ml Pour-on Solution for Cattle

2. Composition

Per ml:

Active substance:

Eprinomectin: 5 mg

Excipients:

Butylated Hydroxytoluene (E321) 0.1 mg

A clear to very light yellow solution.

3. Target Species

Cattle (dairy, for meat production)

4. Indications for use

For treatment and prevention of the following parasites

Gastrointestinal Roundworms (adults and fourth stage larvae):

Ostertagia spp.,

Ostertagia lyrata (adult),

Ostertagia ostertagi (including inhibited *O. ostertagi*),

Cooperia spp. (including inhibited *Cooperia* spp),

Cooperia oncophora,

Cooperia pectinata,

Cooperia punctata,

Cooperia surnabada,

Haemonchus placei,

Trichostrongylus spp.,

Trichostrongylus axei,

Trichostrongylus colubriformis,

Bunostomum phlebotomum,
Nematodirus helvetianus,
Oesophagostomum spp. (adult),
Oesophagostomum radiatum, *Trichuris* spp (adult).

Lungworms (adults and fourth stage larvae):
Dictyocaulus viviparus

Warbles (parasitic stages):
Hypoderma bovis, *H. lineatum*

Mange Mites:
Chorioptes bovis, *Sarcoptes scabiei* var *bovis*

Lice:
Damalinia bovis (biting lice), *Linognathus vituli* (sucking lice),
Haematopinus eurysternus (sucking lice), *Solenopotes capillatus* (sucking lice).

Horn Flies:
Haematobia irritans.

Prolonged Activity

Applied as recommended, the product prevents reinfections with:

Dictyocaulus viviparus (up to 28 days)
Ostertagia spp (up to 28 days)
Oesophagostomum radiatum (up to 28 days)
Cooperia spp (up to 21 days)
Trichostrongylus spp (up to 21 days)
Haemonchus placei (up to 14 days)
Nematodirus helvetianus (up to 14 days)

The following parasite species are included within each of the relevant genera: *Ostertagia ostertagi*, *O. lyrata*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Trichostrongylus axei*, *T. colubroformis*.

5. Contraindications

Do not administer orally or by injection.

Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

Do not use in dogs, as avermectins can cause fatalities in some dog breeds.

6. Special warnings

Special warnings:

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

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.

While mite and louse numbers decline rapidly following treatment, due to the feeding habits of the parasites, in some cases several weeks may be required for complete eradication.

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

For the best results the product should be part of a program 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:

The product should be applied only to healthy skin.

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 skin and eye contact with the product during treatment and when handling recently treated animals.

Personal Protective equipment consisting of gloves, boots and a waterproof coat should be worn when applying the product. Should clothing become contaminated, remove as soon as possible and launder before re-use.

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

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

This product may be toxic after accidental ingestion.

Avoid accidental ingestion of the product by hand to mouth contact.

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

In the event of ingestion, wash out mouth with water and seek medical advice.

Wash hands after use.

This product is flammable. Keep away from sources of ignition.

Inhalation of the product may cause irritation.

Use only in well ventilated areas or outdoors.

Special precautions for the protection of the environment:

Eprinomectin is very toxic to dung fauna and aquatic organisms 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 two to four weeks after treatment.

Pregnancy and lactation :

May be used in dairy cattle during all stages of lactation.

Studies have demonstrated a wide safety margin. Studies conducted at three times the recommended use level of 0.5 mg eprinomectin/kg b.w. had no adverse effect on breeding performance of cows or bulls.

Overdose:

In adult cattle, after administration of 5 times the recommended dose (2.5 mg eprinomectin/kg body weight), mild hair loss was observed. No other signs of toxicity were seen.

No antidote has been identified.

7. Adverse events

Cattle;

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pruritus; Alopecia
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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 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 using the contact details at the end of this leaflet, or via your national reporting system:

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

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

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

Administer only by topical application at the dose rate of 1 ml 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 topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

For best results use as part of a program to control both internal and external parasites of cattle based on the epidemiology of these parasites

9. Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

10. Withdrawal periods

Meat & offal: 10 days

Milk: zero hours.

11. Special storage precautions

Do not store above 30°C.

Keep the container in the outer carton.

Protect from light.

12. 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 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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 02000/4340

The veterinary medicinal product will be supplied in 250mL and 1L containers and 1L, 2.5L and 5L backpacks.

Not all package 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 and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

17. Other information

POM-V (Prescription Only).

Gavin Hall
Approved: 17 April 2026