PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noromectin Pour-on vet. 5 mg/ml, Pour-on solution

2. Composition

1 ml contains:

Active substance:

Ivermectin: 5 mg

Excipient:

Patent blue (E131) 0.005 mg

The solution is clear blue.

3. Target species

Cattle

4. Indications for use

Noromectin Pour-on vet is indicated for treatment of following parasites in cattle:

Gastrointestinal round worms
Ostertagia ostertagi (adult and L4 hypobiotic larvae)
Haemonchus placei (adult and L4)
Trichostrongylus axei (adult and L4)
Trichostrongylus colubriformis (adults and L4)
Cooperia spp. (adults and L4)
Oesophagostomum radiatum (adult and L4)

Lungworms
Dictyocaulus viviparus (adult and L4)

Warbles (parasitic forms)
Hypoderma bovis
Hypoderma lineatum

Lice
Sucking lice
Linognathus vituli
Haematopinus eurysternus
Biting lice
Damalinia bovis

Manage
Chorioptes bovis
Sarcoptes scabiei var. bovis

Flies
Haematobia irritans

5. Contraindications

Animals showing hypersensitivity to ivermectins should not be treated.

6. 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 (an avermectin) has been reported in *Cooperia oncophora* and *Ostertagia ostertagi* in cattle within the EU, in Teladorsagia in cattle in developed countries such as New Zealand and *Haemonchus* in cattle outside the EU. Therefore the 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.

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

This product should only be used in well-ventilated areas or outdoors. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. Avoid contact to skin and eyes. In case of accidental contact to skin wash the affected area immediately with soap and water. In case of accidental eye exposure, flush the eyes immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Noromectin Pour-On can be administered to beef cows at any stage of pregnancy or lactation. Noromectin Pour-On must not be administered to lactating dairy cattle, dry cows or heifers later than 60 days prior to calving, when milk is intended for human consumption.

Other precautions:
In non-target species, ivermectins/milbemycins can be less well tolerated. (Cases of intolerance with fatal consequences have been reported in dogs, particularly collies, Old English Sheepdogs and related breeds and turtles).

Overdose:
No symptoms from overdosing have been reported when 10 times the recommended dose has been used (5 mg per kg bodyweight). No antidote is known.

7. Adverse events

None known.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Topical administration at a dose of 1 ml per 10 kg bodyweight (corresponding to the recommended dose of 0.5 mg per kg bodyweight). The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

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

9. Advice on correct administration

Do not treat cattle when their hide is wet, dirty animals or animals with manage or scab lesions at the site of application, since this might reduce the effect of the product. Rain within two hours following application might also reduce the effect.

10. Withdrawal periods

Meat and offal: 21 days.
Lactating dairy cattle must not be treated.
Dry cows or heifers must not be treated later than 60 days before calving.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C
Keep container in the outer carton in order to protect from light. Inflammable.
Keep the container tightly closed.
The containers should be stored in a stand up position. If stored below 0°C the solution may appear cloudy. Allowing to warm to room temperature will restore the normal appearance without affecting the efficacy.
Do not use cloudy solution.

12. 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 Ivermectin is extremely 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 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

250 and 1000 ml (with dispenser) and 1 l and 2.5 l (collapsible backpacks).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2025-07-02

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co Down
BT35 6JP
Northern Ireland

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information