

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE:

Noromectin Pour-On Veterinary, Topical Solution, 0.5% W/V

2. ACTIVE INGREDIENTS:

Each 1 ml of the medicine contains:
Ivermectin 5mg

The medicine also contains the excipient:

Patent Blue V (E131) 0.0005% w/v

For a full list of excipients, see section 13 "Further information".

3. Indications for use:

For the treatment of gastrointestinal roundworms, lungworms, eyeworm, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef cattle.

Therapeutic group: Avermectins.

4. Contraindications:

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

Formulated for specific use in cattle.

It should not be applied or administered to other species, as severe reactions, including fatalities in dogs, may occur.

5. Adverse reactions:

Undesirable effects are not expected when the product is used at the recommended dose rate.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link: <https://sideeffects.health.gov.il>

6. Target Species: Beef cattle only.

7. Amounts to be administered and administration route:

The medicine should be administered topically at 500 µg per kg bodyweight (1 ml per 10 kg bodyweight).

8. How to use the product:

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tailhead.

2.5 litre pack (Collapsible Back Pack)

- Remove the shipping cap from the backpack container and replace with the vent cap provided.
- Attach the hose from the automatic dosing equipment to the outlet from the vent cap.
- Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

9. Withdrawal period

Do not use 60 days before calving.

Not to be used in cows producing milk for human consumption.

Cattle: Meat: 42 days.

10. Warnings:

- **Special precautions regarding the use of the medicine for the target animal:**

Assess bodyweight as accurately as possible before calculating the dosage.

- **Special precautions regarding the safe use of the medicine in animals:**

For external use only.

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 allow these species to come in contact with this product.

Close container after use.

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.
- Under dosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device. It is recommended to treat all animals within a herd or group.

The shedding of nematode eggs can continue for some time after treatment.

- **Special precautions to be taken by the person administering the product to animals:**

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

Do not eat, drink or smoke while handling the product. Wash hands after use.

Use only in well ventilated areas or outdoors.

- **Additional precautions:**

Highly flammable! Keep away from heat, sparks, open flame or other sources of ignition.

As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

- **Use during pregnancy and lactation:**

Can be administered to beef cows at any stage of pregnancy or lactation.

- **Interactions with other medicinal products and other forms of interaction:**

Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

- **Overdose:**

No signs of toxicity are likely up to 5 mg/kg (10 times the recommended dose rate). There is no known antidote.

- **Incompatibilities:**

None known

11. Storage instructions:

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- **Storage conditions:**

Store at a temperature below 25°C. Protect from light. Store the container in the original box and in upright position.

- After opening of the package, the product should be used up within 12 months. Remains of the product should be discarded after 12 months.

12. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate ponds, waterways or ditches with the product or used containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste.

Do not dispose in sewage.

13. Further Information:

- **In addition to the active ingredient the medicine also contains:**

Crodamol CAP, Triethanolamine, Patent Blue V Dye (E131), Isopropyl Alcohol

- **Pharmaceutical form:**

A clear blue liquid solution.

- **Packaging size:**

Packed in 2.5 Liter bottles.

- **Registration holder and address:**

Abic Veterinary Products Ltd.,
2 Hanegev Street, Airport City, 7019900

- **Manufacturer and address:**

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

Revised in February 2025 according to MoHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
083-58-92345-00