

***This leaflet has been reviewed and approved by the MoH: 7/2018***

**SUMMARY OF PRODUCT CHARACTERISTICS**  
**Veterinarian Prescription only medicine**  
**For animal use only**

**1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE**

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

**2. ACTIVE INGREDIENTS**

Each ml contains:

Ivermectin 5mg (0.5%w/v)

For the full list of excipients, see section 13 "further information"

**3. Indications for use**

Indicated for the effective treatment and control of the following gastrointestinal roundworms, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef

**Gastrointestinal roundworms (adults and fourth stage larvae):**

*Ostertagia ostertagi*, *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia Oncophora*, *C. Punctata*, *Oesophagostomum radiatum*, *O. Venulosum*, *Strongyloides papillosus*, *Trichuris* spp and *Nematodirus* spp

**Lungworms (adult and fourth stage larvae):**

*Dictyocaulus viviparus*.

**Warbles (parasitic stages):**

*Hypoderma bovis*, *Hypoderma lineatum*.

**Mange mites:**

*Chorioptes bovis*, *Sarcoptes scabiei* var *bovis*.

External parasites and Lice :

*Linognathus vituli*, *Haematopinus eurysternus*, *Bovicola bovis* and *Solenopotes capillatus* ,  
Chorioptic and sarcoptic mange mites, Buffalo flies (*Haematobia irritans exigua*) ,Cattle ticks  
(*Boophilus microplus*), *Ostertagia* spp (small brown stomach worms)

**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](http://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:**

This product is only indicated for Cattle.

Not for use in cows which produce milk for human consumption.

#### 7. **Amounts to be administered and administration route**

For external use only.

Recommended dose: 1 ml for each 10 kg body weight.

#### 8. **administration route**

##### 2.5 liter 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**

Cattle: Meat: 42 days.

Not for use in animal producing milk for human consumption.

Not for use in cows producing milk (including pregnant cows) within 60 days of calving.

#### 10. **Special warnings and precautions for use:**

##### **Special warnings concerning the treated animal:**

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result 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 (if any).

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

- Care should be taken to avoid contact with skin and eyes of the user himself or other persons. may be irritating to human skin and eyes.

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.

- Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product.
- Protective clothing should be washed after use.
- Do not eat, drink or smoke while handling the product.
- Wash hands after use. Use only in well ventilated areas or outdoors.
- To be used only in open and ventilated areas

#### **Additional warnings**

Highly flammable – keep away from heat, sparks, open flame or other sources of ignition.

**Interaction with other medicinal products and other forms of interaction**

None

**Overdose**

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

**11. Storage instructions**

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25°C. protect from light.
- Highly flammable – keep away from heat, sparks, open flame or other sources of ignition.
- Shelf-life after first opening the immediate packaging: 12 months. Remedies should be destroyed after 12 months.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

**13. FURTHER INFORMATION:**

**In addition to the active ingredient the product also contains:**

Crodamil CAP, Triethanolamine, Patent Blue V Dye, Isopropyl Alcohol

**Pharmaceutical form:**

- A clear blue liquid solution.
- Packed in a 250ml, 1 Litter and 2.5 Litter bottles.  
Not all package size may be marketed.

**Registration holder:** Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

**Manufacturer:** Norbrook Laboratories Limited, Camlough Road, Newry, Co Down BT35 6JP, Northern Ireland, UK

**Product registration number:** 083-58-92345-00