SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Pour-On Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	**% w/v**
Ivermectin	0.5
Excipient(s):	
Patent Blue V (E131)	0.0005

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on Solution
A clear blue liquid

4. CLINICAL PARTICULARS

4.1 Target species

Beef cattle

4.2 Indications for use, specifying the target species

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 cattle.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp, *Oesophagostomum radiatum, Strongyloides papillosus* (adult)*, Trichuris* spp (adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.

Eyeworms (adult):
Thelazia spp

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

Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis.

Mange mites:
Chorioptes bovis, Sarcoptes scabiei var *bovis*.
Rainfall before or after treatment will not affect the efficacy of Noromectin 0.5% w/v Pour-On Solution.

4.3 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.

4.4 Special warnings for each target species

Assess bodyweight as accurately as possible before calculating the dosage.

4.5 Special precautions for use

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.

Special precautions for use in animals

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in effective 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* 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.

As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.
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 veterinary medicinal product to animals

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

Noromectin Pour-On Veterinary 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.

4.6 Adverse reactions (frequency and seriousness)

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

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction 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.

4.9 Amounts to be administered and administration route

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

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

250 ml bottle and 1 litre pack
(Squeeze dispensing bottle/twin-neck container)

- Remove the cap (twin-neck container) or attach the dispensing cup to the product bottle (squeeze-measure container) and hold the container in an upright position.
- Gently squeeze the container until the product is level with the desired dose volume increment.
- Dispense the product by tipping the container forward until inverted.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Do not use in non lactating dairy cows including pregnant heifers within 60 days of calving.

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

Cattle: Meat: 42 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins

ATC Vet Code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a 22,23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Avermectins act to stimulate GABA mediated chloride ion conductance, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodamol CAP
Triethanolamine
Patent Blue V (E131)
Isopropyl Alcohol

6.2 Major incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf-life after opening the immediate packaging: 1 Year

6.4 Special precautions for storage

Store below 25°C.
Protect from light.
Store in tightly closed original container.
The containers should be stored upright in their original boxes when not in use.
Following withdrawal of the first dose, use the product within 1 year.

6.5 Nature and composition of immediate packaging

250 ml and 1.0 litre natural high density polyethylene twin neck bottle with polypropylene screw cap with woodpulp faced aluminium wad seal.

250 ml and 1.0 litre natural high density polyethylene squeeze bottle with polypropylene screw cap with woodpulp faced aluminium wad seal.

2.5 L white low density polyethylene backpack with polypropylene screw caps with woodpulp faced aluminium wad seal.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 product should be disposed of in accordance with local requirements.

7. MANUFACTURER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION HOLDER

Comex Ltd.
Nablus Road No. 1
P.O.B. 19943, Jerusalem 97200

9. MARKETING AUTHORISATION NUMBER

083-58-92345-00

Revised in January 2023 according to MoH’s guidelines.