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 Injection Veterinary, 1% W/V, Solution for injection, S.C

2. ACTIVE INGREDIENTS
Each ml contains:
Ivermectin 10 mg

For the full list of excipients, see section 12 “further information”

3. Indications for use
For the treatment and control of the following parasites of beef, sheep and non-lactating dairy cattle as detailed bellow:

Cattle:
- Treatment and control of **gastrointestinal roundworms** (adult and L4 stage larva): Ostertagia ostertagi (including inhibited large stage), Osertagia Lyrata, Heamonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia punctana, Cooperia pectinate, Cooperia oncophora, Bunostomus phlebotomun, Oesophagostomum radiatum, Strongyloides papillosus (adult), Nematodirus spathiger(adult), Nematodirus helvetianus (adult), Trichuris spp (adult).
- **Lungworms** (adult and L4 stage larva): Dictyocaulus viviparous
- **Eyeworms** (adult): Thelazia spp
- **Warbles**: Hypoderma bovis, Hypoderma lineatum
- Sucking lice: Linognathus vituli, Heamatopinus eurysternus, Solenopotes capillatus
- Manage Mites: Psoroptes Ovis, Sarcoptes Scabei Var. bovis

Sheep:
-Manage Mites :Psorptes ovis
-Nasal bots (all larveal stage): Oestrus ovis
- Treatment on **gastrointestinal roundworms** (adult and L4 stage larva): Ostertargia circumcincta, o. Trifurcata, Heamonchus contortus, Trichostrongylus axei (adult), Trichostrongylus colubriformis, Trichostrogylus vitrines (adults), cooperia curticei, Oesophagostomum venulosum, Oestophagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichuris ovis (adults).
- Benzimidazole-resistant strains of :Haemonchus controtus -ı Oestertagia circumcinacta
- Lungworms: Dictyocaulus fialria (adults and fourth stage larvae), Photostrongylus rufescens (adults).

4. Contraindications
Do not inject intravenously or intramuscularly. For S.C only.

The product is specifically for use in the target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

5. Adverse reactions

Mild and transient discomfort has occasionally been observed in cattle and few sheep following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These symptoms pass without treatment. If they do not pass, or if other symptoms occur, please consult your veterinary.

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://forms.gov.il/forms/Resources/DowloadSetup/AGFormsDownloadToolbar.htm?formid=AdversEffectMedic@moh.gov.il

6. Target Species:

Cattle, Sheep

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

7. Amounts to be administered and administration route

Noromectin Injection Veterinary should be given only by subcutaneous injection at the recommended dosage level of 200 mcg Ivermectin per kg bodyweight.

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

Each milliliter contains 10mg Ivermectin sufficient for treatment of 50kg animal bodyweight.

Use this chart as a guide in working out the appropriate dose rate:

Cattle:

BodyWeight (kg)	Dosage volume (ml)	BodyWeight (kg)	Dosage volume (ml)
Up to 50	1.0	301-350	7.0
51-100	2.0	351-400	8.0
101-150	3.0	>400	Dosage should be calculated by giving 1ml for each 25kg animal bodyweight
151-200	4.0		
201-250	5.0		
251-300	6.0		

To be injected under the loose skin in front of, or behind, the shoulder

Sheep:

BodyWeight (kg)	Dosage volume (ml)	BodyWeight (kg)	Dosage volume (ml)
Up to 5	0.1	25.1-50	1.0
5.1-10	0.2	50.1-75	1.5
10.1-15	0.3	75.1-100	2.0
15.1-25	0.5	>100	Dosage should be calculated by giving 1ml for each 25kg animal bodyweight

To be injected under the loose skin in front of, or behind the neck.

When treating sheep of less than 16kg, seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml. For the treatment of individual sheep, a syringe not exceeding 2.0ml and calibrated in increments of 0.1ml should be used.

In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although clinical improvement may be seen, elimination of all mites may not occur.
In such cases, two injections with a seven day interval are required to treat clinical signs of scab and to eliminate mites.

Use of a sterile 17 gauge x 15-20mm needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended.

8. Withdrawal period

Cattle: Meat: 49 days.
Sheep:Meat: 42 days.
Not for use in cattle producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant heifers, 60 days before calving.
Not for use in animal producing milk for human consumption.

9. Special warnings and precautions for use:

Care should be taken to avoid parasite resistance to the product due to frequent and repeated use of the drug or the preparations from the same family, or from under dosing resulting from an underestimation of body weight of the animal, giving the wrong medicine or the wrong calibration of the dosing syringe.
Therapy should be based on local epidemiological information (regional, farm) to limit this possible resistance to this kind of medicine.

- Special precautions for use in animals:

Sheep scab (Psoroptes ovis) is an extremely contagious external parasite of sheep. To ensure complete control great care must be taken to avoid re–infestation, as mites may be viable for up to 15 days off the sheep. It is important that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and untreated flocks must be avoided until at least seven days after treatment.

- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
  - Do not smoke, drink or eat while handling the product.
  - Wash hands after use.
  - Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of injection.
  - In case of accidental self-injection, seek medical advice and show the label or package leaflet to the physician.
- Use during pregnancy, lactation or lay
  - Can be safely administered during pregnancy and lactation, provided that the milk is not intended for human consumption.
  - Can be given to all ages of animals including young calves and lambs.
- Interaction with other medicinal products and other forms of interaction:
  - In the absence of appropriate studies, do not use this medicine together with other veterinary medicines.
- Overdose:
  - Single doses of 4.0 mg Ivermectin per kg (20 x the use level) given subcutaneously (both in Sheep and in cattle) resulted in ataxia and depression.
  - No antidote has been identified; however, symptomatic therapy may be beneficial.

10. 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^{o}c. protect from light.
- Shelf-life after first opening the immediate packaging: 28 days. Remedies should be destroyed after 28 days.

11. 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.

12. FURTHER INFORMATION:

In addition to the active ingredient the product also contains:

Glycerol formal, Polyethylene glycol

Pharmaceutical form:

- Sterile non- aqueous solution. Packed in a 50,100,250,500 ml volume LDPE bottle.

Registration holder: :Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200
Manufacturer: Norbrook Laboratories Limited, Armagh Road, Newry, Co Down BT35 6QQ, Northern Ireland, UK
Product registration number: 081-28-92218-00