Veterinary Medicine User Leaflet
Veterinarian Prescription only medicine • For animal use only **EN**

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE:
Noromectin Paste for Horses Veterinary

2. ACTIVE INGREDIENTS:
Each syringe contains: Ivermectin 1.87% w/w
Excipients: Titanium Dioxide 2.0% w/w
For a full list of excipients, see section 13 "further information".

3. Indications for use:
The product is indicated for the treatment of parasitic infestations in horses and donkeys due to:

Large strongyles:	*Strongylus vulgaris*	adults and larval (arterial) stages
	Strongylus edentatus	adults and larval (tissue) stages
	Strongylus equinus	adults
	Triodontophorus spp	adults
Small strongyles	*Cyathostomum spp*	adult and immature
Including benzimidazole-	*Cylicocyclus spp*	adult and immature
Resistant strains	*Cylicodontophorus spp*	adult and immature
	Gyalocephalus spp	adult and immature
Hairworms	*Trichostrongylus axei*	adult
Pinworms	*Oxyuris equi*	adult and immature
Ascarids	*Parascaris equorum*	adult and immature
Intestinal threadworms	*Strongyloides westeri*	adult
Neck threadworms	*Onchocerca* spp	microfilariae
Lungworms	*Dictyocaulus arnfieldi*	adult and immature
Stomach bots	*Gasterophilus spp*	oral and gastric larval stages
	Habronema muscae	adult

Therapeutic group: broad spectrum anthelmintic drug.

4. Contraindications: Do not use this medicine if the animal is sensitive (allergic) to the active ingredient, the group of substances macrocyclic lactones, to which the active ingredient belongs, or to any of the excipients.
This medicine is only suitable for use in horses and donkeys. Do not administer it to other animals as it may cause severe side effects. Do not administer to dogs and cats, and do not let them lick the paste or the used syringe.

5. Adverse reactions (frequency and seriousness): Some horses carrying heavy infection of Onchocerca microfilariae have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable. 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: Horses and donkeys.

7. Amounts to be administered and administration route:
Administer orally to both horses and donkeys at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Each syringe delivers 140 mg ivermectin, sufficient to treat 700 kg of bodyweight. To ensure administration of a correct dose, body weight should be determined as accurately as possible; each scale in the syringe is suitable for dose given for 100 kg of body weight. Retreatment should be carried out according to the epidemiological situation, but not less than at a 30 day interval.

8. How to use the preparation: The animal's mouth should be free of food to ensure swallowing. The tip of the syringe barrel should be inserted at the interdental space (the gap between front and back teeth). The horses head should be raised for a few seconds after dosing. For best results all horses in a yard should be treated at the same time.

9. Withdrawal period: Not relevant.

10. Special warnings and precautions for use:
- Special precautions regarding the use of the medicine for the target animals:
  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 anthelmintic 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.
- Special safety precautions regarding the use of the medicine in animals: None.
- 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.
  - Avoid contact of the product with the skin or eyes. In case of contact, rinse immediately with plenty of water.
  - Wash hands after use.
  - In case of ingestion or eye irritation, seek medical advice and show the syringe or the product leaflet to the physician.
- Additional precautions:
  The medicine is extremely dangerous to fish and aquatic life. Do not contaminate lakes, pools or waterways by disposing of the medicine or unused medicine in them.
- Pregnancy and lactation:
  The medicine may be administered to pregnant and lactating animals. Additionally, it may be used in breeding stallions without adversely affecting their fertility.
- Interaction with other medicinal products and other forms of interaction: When the medicine was administered in conjunction with other equine health care products, no interactions with the other products were observed.
- Overdose: Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.
- Incompatibilities:
  In the absence of data, do not mix this medicine with other medicines.

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 exp. date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25ºC. Store in the original box to protect from light.
- Use immediately after opening and dispose of the unused medicine.

12. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:
The medicine is extremely dangerous to fish and aquatic life. Do not contaminate lakes, pools or waterways by disposing of the medicine or unused medicine in them. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of in sewage.

13. FURTHER INFORMATION:
- **In addition to the active ingredient the product also contains:**
  Hydroxypropyl Cellulose, Hydrogenated Castor Oil, Titanium Dioxide (E171), Propylene Glycol, Water for Injection
- **Pharmaceutical form:**
  A white homogenous oral paste, packed in a single time use syringe.
- **Packaging sizes:** LDPE syringe with 7.49 gr of paste, packed in boxes of 1, 2 and 10 units. Not all pack sizes may be marketed.
- **Registration holder:** Abic Veterinary Products Ltd.,
  2 Hanegev Street, Airport City, 7019900
- **Manufacturer:** Norbrook Laboratories Limited,
  Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

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- **Registration number of the medicine in the National Registry of the Ministry of Health:** 082-50-92296-00