DRAFT LABEL

NOROMECTIN 1.87% ORAL PASTE FOR HORSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROMECTIN 1.87% Oral Paste for Horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 1.87%% w/w

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

Syringes containing 7.49 g of product in cartons of 1, 2, 10 and 50 syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Noromectin 1.87% Oral Paste for Horses provides treatment of the important internal parasites of horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IMPORTANT: Read carton text before use.

8. WITHDRAWAL PERIOD

Meat and offal: 34 days

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: Read carton text before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Keep the container in the outer carton in order to protect from light. This is a unidose product which should be disposed of after use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Any unused product or waste material should be disposed of in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer and VPA

Holder: Distributed by:

16. MARKETING AUTHORISATION NUMBER

Vm 02000/3001

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM
:

DRAFT CARTON

NOROMECTIN 1.87% ORAL PASTE FOR HORSES
(1.87% w/w Ivermectin)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROMECTIN 1.87% ORAL PASTE FOR HORSES

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin	1.87% w/w

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

Syringes containing 7.49 g of product in cartons of 1, 2, 10 and 50 syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Noromectin 1.87% Oral Paste for Horses kills the adult and some larval stages of the important internal parasites of horses. Noromectin 1.87% Oral Paste for Horses at the recommended dose rate of 200 μg ivermectin per kg bodyweight is indicated for the treatment of the following internal parasites of horses:

Large strongyles (redworms): adults and 4th larval (arterial) stages of *Strongylus vulgaris*, adults and tissue larval stages of *S. edentatus* and adults of *S. equinus*.
Adult small strongyles (redworms) including benzimidazole resistant strains: *Cyathostomum catinatum, Cyathostomum pateratum, Cylicocyclus ashworthi, Cylicocyclus elongatus, Cylicocyclus insigne, Cylicocyclus leptostomum, Cylicocyclus nassatus, Cylicocyclus radiatus, Cylicostephanus asymetricus, Cylicostephanus bidentatus, Cylicostephanus calicatus, Cylicostephanus goldi, Cylicostephanus longibursatus, Cylicostephanus minutus, Cylicodontophorus bicornatus* and *Gyalocephalus capitatus*.
Adult and immature lungworms: *Dictyocaulus arnfieldi*
Pinworms: Adult and immature *Oxyuris equi*
Ascarids: Adult and 3rd and 4th stage *Parascaris equorum*
Hairworms: Adult *Trichostrongylus axei*
Intestinal threadworms: Adult *Strongyloides westeri*
Neck threadworms: Microfilariae of *Onchocerca* spp
Oral and gastric larval stages of stomach bots: *Gasterophilus* spp.

Ivermectin is not effective against encysted larval stages of the small strongyles.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Noromectin 1.87% Oral Paste for Horses is administered orally at a single dose rate of 200 μg/kg of bodyweight. One syringe division of paste should be administered per 100 kg bodyweight (based on the recommended dosage of 200 μg/kg). Each syringe delivers 140 mg ivermectin, sufficient to treat 700 kg of bodyweight. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth). The horse's head should be raised for a few seconds after dosing.
Horses' weight should be accurately determined for the correct use of the paste. The animal's mouth should be free of food to ensure swallowing.
For best results all horses in a yard or grazing together should be included in a regular parasite control programme and treated at the same time.

All horses should be included in a regular parasite control programme, with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6-8 weeks of age and routine treatment repeated as appropriate. Retreatment should be carried out according to the epidemiological situation, but not less than at a 30 day interval.

Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other on the same premises.

As with all anthelmintics, a veterinary surgeon should establish appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Horses must not be treated within 34 days of slaughter for human consumption. Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For animal treatment only.

Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher 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. Although no antidote has been identified, symptomatic therapy may be beneficial.

Noromectin 1.87% Oral Paste for Horses has been formulated for use in horses only. Dogs and cats may be adversely affected by the concentration of ivermectin in the product if they are allowed to ingest spilled paste or have access to used syringes.

Do not smoke or eat while handling the product. Wash hands after use. Avoid eye contact. This is a unidose product which should be disposed of after use.

Frequent and repeated use may lead to the development of resistance.

Do not use in dogs or cats as severe adverse reactions may occur.

Some horses have experienced reactions involving cutaneous swelling and itching shortly after treatment. In most of these cases, the horses have been diagnosed as carrying heavy infections of *Onchocerca* microfilariae, and it is assumed the reactions are a result of the microfilariae dying in large numbers. Although the signs will resolve spontaneously in a few days, symptomatic treatment may be advisable. Consult your veterinary surgeon should these signs persist.

Horses of all ages, including young foals, pregnant mares and breeding stallions have been treated with no adverse effects on their health and fertility. Ivermectin passes readily into milk. When administering to lactating females, residues of ivermectin could be present in the maternal milk. No studies have been reported on the effect of ingestion of milk on the development of newborn foals.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C. Keep the container in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface water or ditches with product or used containers. Any unused product or waste material should be disposed of in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

Manufacturer Responsible for Batch Release:
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Ltd.
Station Works
Newry
Co Down, BT 35 6JP
Northern Ireland

Distributed By:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/3001

17. MANUFACTURER'S BATCH NUMBER

B.N.:

LOGO

Approved 02 November 2023