SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 1.87% Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ivermectin 1.87% w/w (18.7 mg/g)

Excipient(s)
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Paste
A white homogenous paste.

4. CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For the treatment of the following parasites of horses:
Roundworms in the stomach and intestines
Large strongyles Strongylus vulgaris adults and 4th larval (arterial) stages
Strongylus edentatus adults and 4th larval (tissue) stages
Strongylus equinus adults
Small strongyles, adults Cyathostomum catinatum
Cyathostomum peteratum
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
Gyalocephalus capitatus
Hairworms Trichostrongylus axei adult
Pinworms Oxyuris equi adult and immature
Ascarids Parascaris equorum adult and 3rd and 4th stage
Intestinal threadwormsStrongyloides westeriadult
Neck threadworms Onchocerca spp (microfilariae)
Lungworms Dictyocaulus arnfieldi adult and immature
Stomach bots Gasterophilus spp oral and gastric larval stages

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

4.3 Contraindications

Do not use in horses known to be hypersensitive to the active ingredient or to any other ingredients.

Do not use in dogs or cats as severe adverse reactions may occur.
See also 4.11

4.4 Special warnings for each target species

The veterinary medicinal product has been formulated specifically for use in horses only. Dogs and cats may be adversely affected by the concentration of ivermectin in the veterinary medicinal product if they are allowed to ingest spilled past or have access to used syringes.

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.

4.5 Special precautions for use

Special Precautions for use in animals:

Avermectins may not be well tolerated in all non-target species (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).

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

Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.
Avoid eye contact.

4.6 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.

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

4.7 Use during pregnancy, lactation or lay

The veterinary medicinal product can be administered at any stage of pregnancy.

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.

Do not use in mares producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

The veterinary medicinal product 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 (0.2 mg/kg). Each syringe delivers 140 mg ivermectin, sufficient to treat 700 kg of bodyweight. Horses weight should be accurately determined for the correct use of the paste. The animal's mouth should be free from food to ensure swallowing. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth). Immediately elevate the horse's head for a few seconds to ensure swallowing.

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.

For best results all horses in a yard or grazing together should be included in a regular parasite control programme, with particular attention being paid to mares, foals and yearlings, and treated at the same time. Foals should be treated initially at 6-8 weeks of age and routine treatment repeated as appropriate.

Retreatment should be done according to the epidemiological situation, but not less than 30 days intervals.

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

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.

4.11 Withdrawal period(s)

Meat and offal: 34 days.

Not permitted in mares producing milk for human consumption.

5. PHARMACOLOGICAL or IMMUNOLOGICAL 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 nemotocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals. Ivermectin is not effective in liver fluke and cestode infestations.

Avermectin bind selectively with glutamate-gated chloride ion channels, which occur in invertebrate nerve or muscle cells. This leads to an increase of the cell membrane permeability to chloride ions of the nerve or muscle cells, causing irreversible neuromuscular blockade in the parasite, followed by paralysis and death.

Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). Ivermectin stimulates GABA liberation at presynaptic nerve terminations (in Nematodes) or the neuromuscular junctions (in Arthropodes), that leads to the paralysis and death of the relevant parasites.

Resistance to ivermectin in horses has not been reported, however it is possible that frequent and repeated use may lead to the development of resistance.

5.2 Pharmacokinetic particulars

After oral administration of the recommended dose to horses, the following parameters were observed: Cmax of 29 ng/ml, Tmax of 7 h, AUC of 1485 ng/ml.h and t½ of 55 h. Ivermectin is highly lipophilic and has good ability to penetrate to the location of parasites. It is stored in and slowly released from fat after which it is converted by the liver to less lipid soluble metabolites by oxidative biotransformation. The excretion route of the active substance occurs mainly in the bile and faeces. Less than 2% is eliminated via urine. Ivermectin is highly protein bound and clearance is slow.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl Cellulose
Hydogenated Castor Oil
Titanium Dioxide (E171)
Propylene Glycol
Water for Injection

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
This is a unidose product. Please dispose of after use.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Low-density polyethylene pre-filled syringes containing 7.49 g of product in cartons of 1,2,10 and 50 syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
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Camlough Road
Newry
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BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/5009

9. DATE OF FIRST AUTHORISATION

28 October 2002

10. DATE OF REVISION OF THE TEXT

November 2023

Approved 02 November 2023