1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 18.7 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hydroxypropyl Cellulose	
Hydrogenated Castor Oil	
Titanium Dioxide (E171)	20 mg
Propylene Glycol	
Water for Injections	

A white homogenous paste.

3. CLINICAL INFORMATION

3.1 Target Species

Horses.

3.2 Indications for use for each 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 threadworms	*Strongyloides westeri*	adult
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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

Ivermectin is extremely dangerous to fish and aquatic life. See section 5.5.

Other precautions:

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 paste or have access to used syringes.

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).

3.6 Adverse reactions (frequency and seriousness)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Oedema[1]; Pruritus[1].

[1] In horses carrying heavy infection of *Onchocerca microfilariae*, assumed to be as a result of death of the parasites. Resolves within a few days but symptomatic treatment may be advisable.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
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.

Fertility:
Horses of all ages, including young foals, pregnant mares and breeding stallions have been treated with no adverse effects on their health and fertility.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Amounts to be administered and administration route

Oral use.

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. To ensure a correct dosage, body weight should be determined as accurately as possible. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restriction on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal Periods

Meat and offal: 34 days.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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.

Avermectins 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.

4.3 Pharmacokinetics

After oral administration of the recommended dose to horses, the following parameters were observed: C_{max} of 29 ng/ml, T_{max} of 7 hours, AUC of 1485 ng/ml.hr and t½ of 55 hours. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.

Keep the container in the outer carton in order to protect from light.

This is a unidose product. Please dispose of after use.

5.4 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.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with product or used containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/062/001

8. DATE OF FIRST AUTHORISATION

06/04/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).