SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

Noromectin 1.87% Oral Paste for Horses (All CMS except IT)
F. Mectin Pasta Orale 1.87% per cavalli (IT)

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 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	
	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.

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 paste 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 **Interactions with other medicinal products and other forms of interaction:**

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 interval.

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):**

Edible tissues: 34 days

Not permitted in mares producing milk for human consumption.

5. Pharmacological 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 nematocidal, 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.

5.2 Pharmacokinetic Properties:

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 Excipient(s):

Hydroxypropyl Cellulose
Hydrogenated Castor Oil
Titanium Dioxide (E171).
Propylene Glycol

6.2 Incompatibilities:

Not applicable.

6.3 Shelf-Life:

36 months
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, and 10 syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 material should be disposed of in accordance with national requirements.

7. Marketing Authorisation Holder

Norbrook Laboratories Limited
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Northern Ireland

8. Marketing Authorisation Number

Vm 02000/4208

9. **Date of Renewal of the Authorisation**

28th October 2007

10. **Date of Revision of the Text**

March 2007