1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 18.7 mg/g Oral Paste for Horses (AT, BE, FR, IE, IS, LU, NL, PT, UK)
Noromectin 18.7 mg/g Oral Paste for Horses (DE, ES, FI)
Noromectin vet., Oral Paste for Horses (DK, SE)
F.Mectin Pasta Orale 1.87% per Cavalli (IT)

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

{DD/MM/YYYY}

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*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 18.7 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. PACKAGE SIZE

7.49 g
1, 2, 10 and 50 syringe(s).

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 34 days

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 18.7 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 34 days
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noromectin 18.7 mg/g Oral Paste for Horses

2. Composition

Each gram contains:

Active substance:

Ivermectin 18.7 mg

Excipients:

Titanium dioxide (E171) 20 mg

A white homogenous paste.

3. Target species

Horses.

4. Indications for use

The veterinary medicinal product kills the adult and some larval stages of the important internal parasites of horses. The veterinary medicinal product 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 catinatium, Cyathostomum pateratum, Cylicocyclus ashworthi, Cylicocyclus elongatus, Cylicocyclus insigne, Cylicocyclus leptostomum, Cylicocyclus nassatus, Cyllicocyclus 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 *Paracaris 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.

5. 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.

6. Special warnings

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

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 12.

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 past 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).

Pregnancy:

Can be used during pregnancy.

Lactation:

Ivermectin passes readily into milk. When administering to lactating females, residues or 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.

Overdose:

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

(dilated pupils), ataxia (incoordination), tremors (shaking), stupor (lethargy), coma and death. The less severe signs have been transitory.

Although no antidote has been identified, symptomatic therapy may be beneficial.

7. Adverse events

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

[1] In horses carrying heavy infection of *Onchocerca microfilariae*, 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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). Each syringe delivers 140 mg ivermectin, sufficient to treat 700 kg of bodyweight.

9. Advice on correct administration

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.

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.

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 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.

10. Withdrawal periods

Meat and offal: 34 days.

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

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

This is a unidose product which should be disposed of after use.

12. Special precautions for disposal

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

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Carton with 1, 2, 10 or 50 syringes containing 7.49 g of product.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

(EU)

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate

Monaghan
Ireland

(UK)

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer responsible for batch release:

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information