1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noropraz, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:
Ivermectin 18.7 mg
Praziquantel 140.3 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hydrogenated castor oil	
Hydroxypropylcellulose	
Titanium dioxide (E171)	20 mg
Apple Flavour	
Propylene glycol	

A white to off white homogenous paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment of mixed cestode and nematode or arthropod infestations, due to adult and immature roundworms, lungworms, bots and tapeworms in horses:

Nematodes:
Large strongyle:
Strongylus vulgaris (adult and arterial larvae),
Strongylus edentatus (adult and L4 tissue larval stages),
Strongylus equinus (adult),
Tridontophorus spp. (adult).

Small strongyle:
Cyathostomum: Cylicocyclus spp.,
Cylicostephanus spp.,
Cylicodontophorus spp.,
Gyalocephalus spp. (adult and non-inhibited mucosal larvae).

Parascaris*: Parascaris equorum* (adult and larvae),

Oxyuris: *Oxyuris equi* (larvae),
Trichostrongylus: *Trichostrongylus axei* (adult),
Strongyloides: *Strongyloides westeri* (adult),
Habronema: *Habronema* spp. (adult),
Onchocerca: *Onchocerca* spp. microfilariae i.e. cutaneous onchocerciasis,
Lungworm: *Dietyocaulus arnfieldi* (adult and larvae).

Cestodes (Tapeworm):
Anoplocephala perfoliata (adult),
Anoplocephala magna (adult),
Paranoplocephala mamillana (adult).

Dipteran insects:
Gasterophilus spp. (larvae).

3.3 Contraindications

Do not use in foals under 2 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Resistance to ivermectin (an avermectin) has been reported in *Parascaris equorum* in horses in a number of countries including in the EU. Therefore the use of this product should be based on local {regional farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics. Therefore the use of this product should be based on local (regional farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.
As tapeworm infestation is unlikely to occur in horses before two months of age, treatment of foals below this age is not considered necessary.

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:

Wash hands after use.
Do not eat, drink or smoke while handling this product.
Avoid contact with the eyes as the product may cause eye irritation.
In case of accidental eye contact rinse immediately with plenty of water.
In case of accidental ingestion or eye irritation, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Avermectins may not be well tolerated in all non-target animals. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles and tortoises.
Dogs and cats should not be allowed to ingest spilled paste or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Swelling[1], Anorexia[2], Itching; Colic[2, 3], Diarrhoea[2, 3], Allergic reaction[4] (such as Hypersalivation, Tongue oedema, Urticaria, Tachycardia, Congested mucous membranes, Cutaneous oedema)

[1] In horses carrying heavy infection of *Onchocerca microfilariae*, assumed to be as a result of the destruction of large number of microfilariae.
[2] Caused by destruction of parasites in cases of very high levels of infestation.
[3] Mild and transient.
[4] A veterinarian should be consulted if these signs persist.

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 and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
Single administration.

200 µg of lvermectin and 1.5 mg of Praziquantel per kg of bodyweight corresponding to 1.07 g of paste per 100 kg bodyweight.

To ensure administration of a correct dosage, bodyweight should be determined as accurately as possible and the correct syringe division selected, as underdosing might lead to an increased risk of development of resistance to anthelmintic drugs.

Weight	Dosage	Weight	Dosage
Up to 100 kg	1.070 g	401 – 450 kg	4.815 g
101 – 150 kg	1.605 g	451 – 500 kg	5.350 g
151 – 200 kg	2.140 g	501 – 550 kg	5.885 g
201 – 250 kg	2.675 g	551 – 600 kg	6.420 g
251 – 300 kg	3.210 g	601 – 650 kg	6.955 g
301 – 350 kg	3.745 g	651 – 700 kg	7.490 g
351 – 400 kg	4.280 g		

The first division delivers enough paste to treat 50 kg.
Each subsequent syringe division delivers enough paste to treat 50 kg of bodyweight. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.
The syringe contains 7.49 g of paste and delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Directions for use

Before administration, ensure the plunger is aligned at 0 at the base of the syringe; if the 0 is sitting above the base of the syringe, prime the syringe by expressing the plunger until the 0 is aligned at the base of the syringe. Adjust the syringe to the calculated dosage by setting the ring on the plunger the front face of the ring should be in line with the market beside the required dose. Care should be taken to ensure the ring has not moved from its set position prior to pressing down on the plunger. The paste is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of the paste on the back of the tongue. The animal's mouth should be free of any food. Immediately after administration, elevate the head of the horse for a few seconds to ensure the dose is swallowed.
The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

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

A tolerance study performed in foals from 2 weeks of age with doses up to 5 times the recommended dosage showed no adverse reactions.
Safety studies conducted in mares administered 3 times the recommended dosage at 14 day intervals during the whole gestation and lactation did not show any abortions, any adverse effects on the gestation, parturition and on the mares general health, nor any abnormalities on the foals.
Safety studies conducted in stallions administered 3 times the recommended dosage did not show any adverse effects in particular on the reproductive performances.

3.11 Special restrictions for use and special conditions for use, including restrictions 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 & Offal: 35 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 54AA51

4.2 Pharmacodynamics

lvermectin is a macrocyclic-lactone derivative which has a broad antiparasitic activity against nematodes and arthropods. It acts by inhibiting nerve impulses. Its mode of action includes the glutamate-gated chloride ion channels. lvermectin binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels.

Praziquantel is a pyrazinoisoquinoline derivative which exerts its anthelmintic activity against many species of cestodes and trematodes. It primarily acts by impairing both motility and function of the suckers of cestodes. Its mode of action includes the impairing of neuromuscular co-ordination but also influencing the permeability of the integument of the worms, which leads to excessive calcium and glucose loss. This induces spastic paralysis of the parasite musculature.

4.3 Pharmacokinetics

After administration of the recommended dosage to horses, the ivermectin plasma peak was reached within 24 hours. The ivermectin concentration was still over 2 ng/ml 14 days after administration. The elimination half-life of ivermectin was 90 hours. The elimination half-life of praziquantel was 40 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 25 °C.
After use, replace cap.

5.4 Nature and composition of immediate packaging

An adjustable multidose oral syringe composed of polyethylene barrel, plunger and end cap, with polypropylene dosing rings. The oral syringe contains 7.49 g of product and is fitted with variable dose capacity.
The oral paste is available in the following pack sizes:

- 1 carton box containing 1 x 7.49 g oral syringe
- 1 carton box containing 2 x 7.49 g oral syringes
- 1 carton box containing 12 x 7.49 g oral syringes
- 1 carton box containing 40 x 7.49 g oral syringes
- 1 carton box containing 48 x 7.49 g oral syringes
- 1 carton box containing 50 x 7.49 g oral 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.

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)

VPA22664/117/001

8. DATE OF FIRST AUTHORISATION

27/09/2013

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

07/10/2026

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).