# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX LABELLING}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. STATEMENT OF ACTIVE SUBSTANCES

**Active Substance**:
Ivermectin 18.7 mg/g
Praziquantel 140.3 mg/g

## 3. PACKAGE SIZE

1 x 7.49 g oral syringe.
2 x 7.49 g oral syringes.
12 x 7.49 g oral syringes.
40 x 7.49 g oral syringes.
48 x 7.49 g oral syringes.
50 x 7.49 g oral syringes.

## 4. TARGET SPECIES

Horses.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral Use

## 7. WITHDRAWAL PERIODS

Meat & Offal: 35 days
Not authorised for use in animals producing milk for human consumption.

## 8. EXPIRY DATE

Exp {mm/yyyy}
Shelf-life after first opening the immediate packaging: 6 months.
Once opened, use by…

## 9. SPECIAL STORAGE PRECAUTIONS

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

## 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

**UK(GB)**
Norbrook Laboratories Limited

## 14. MARKETING AUTHORISATION NUMBERS

Vm 02000/4365

## 15. BATCH NUMBER

Lot {number}

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {SYRINGE LABELLING}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noropraz

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g
Praziquantel 140.3 mg/g

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate packaging: 6 months.
Once opened, use by…

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

Each gram contains:
**Active substance:**
Ivermectin 18.7 mg
Praziquantel 140.3 mg

A white to off white homogenous paste.

### 3. Target species

Horses.

### 4. Indications for use

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).

## 5. 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.

## 6. Special warnings

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.

As tapeworm infestation is unlikely to occur in horses before two months of age, treatment of foals below this age is not considered necessary.

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 label to the physician.

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 turtle 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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Overdose:
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.

## 7. Adverse events

Target species: Horses.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Swelling[1], Anorexia (loss of appetite)[2],<br>Itching[1]<br>Colic[2,3], Diarrhoea[2, 3],<br>Allergic reaction[4] (such as Hypersalivation[3], Tongue oedema[3] (swelling) Urticaria (hives), Tachycardia (rapid heart rate), Congested mucous membrane[3], Cutaneous oedema (skin swelling)). |

[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 level 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 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use.

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

To ensure 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.

## 9. Advice on correct administration

Before administration, adjust the syringe to the calculated dosage by setting the ring 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.

## 10. Withdrawal periods

Meat & Offal: 35 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.
After use, replace cap.

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

Shelf life after first opening the immediate packaging: 6 months.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as iveremctin may be 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 applicable national collection systems. These measures should help to protect the environment.

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

## 13. Classification of veterinary medicinal products

| |
|---|
| POM-VPS |

Prescription Only Medicine

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/4365

The oral paste is available in the following pack sizes:
- 1 carton box containing 1 x 7.49g oral syringe
- 1 carton box containing 2 x 7.49g oral syringes
- 1 carton box containing 12 x 7.49g oral syringes
- 1 carton box containing 40 x 7.49g oral syringes
- 1 carton box containing 48 x 7.49g oral syringes
- 1 carton box containing 50 x 7.49g oral syringes

Not all pack sizes may be marketed.

## 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

## 16. Contact details

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

(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
United Kingdom
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
United Kingdom

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

## 17. Other information

POM-VPS

*Gavin Hall*
Approved: 23 April 2025