MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe Labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin 18.7 mg/g
Praziquantel 140.3 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

7.49 g

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD
Horses: Meat & Offal: 35 days
Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 6 months

Once opened, use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only

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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 for Horses
Ivermectin and Praziquantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Substance:

Ivermectin	18.7 mg/g
Praziquantel	140.3 mg/g

Excipient(s):

Titanium Dioxide (E171)	20 mg/g

3. PHARMACEUTICAL FORM

Oral paste

4. 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

5. TARGET SPECIES

Horses

6. INDICATION(S)

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

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
9. SPECIAL WARNING(S), IF NECESSARY

Oral Use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal Period
Horses: Meat & Offal: 35 days
Not authorisedfor use in horses producing milk for human consumption.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 6 months
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.
After use, replace cap and store below 25^{o}C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4365

17. MANUFACTURER'S BATCH NUMBER

BN

PACKAGE LEAFLET
Noropraz, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses
Ivermectin and Praziquantel

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:
Active substance:

Ivermectin	18.7 mg
Praziquantel	140.3 mg
Excipient(s):	
Titanium Dioxide (E171)	20 mg

A white to off white homogenous paste

4. INDICATION(S)

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: *Dictyocaulus 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 case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Horses carrying heavy infection of *Onchocerca microfilariae* have experienced such reactions as swelling and itching after treatment. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.
In case of very high levels of infestation, destruction of the parasites may cause a mild transient colic and loose faeces in the treated horse.
Colic, diarrhea and anorexia have been reported in very rare occasions post treatment, in particular when there is heavy worm burden.
In very rare occasions, allergic reactions such as hypersalivation, lingual oedema and urticaria, tachycardia, congested mucus membranes, and subcutaneous oedema have been reported following treatment with the product. A veterinarian should be consulted if these signs are present.t
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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For 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 administration of a correct dose, 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 PERIOD

Horses: Meat & Offal: 35 days
Not authorisedfor use in horses 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 and store below 25°C.
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 WARNING(S)

Special precautions for use in animals:
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.

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.

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

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used syringes.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2019

15. OTHER INFORMATION

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.

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Approved 31 July 2019