

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box containing 1 x 7.49 g or 10 x 7.49 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nexpraz Duo 18.7 mg/g + 140.3 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	18.7 mg/g
Praziquantel	140.3 mg/g

3. PACKAGE SIZE

1 x 7.49 g
10 x 7.49 g

4. TARGET SPECIES



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 35 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.
Once opened, use by...

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the applicator tightly closed. Replace the cap 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

Bioveta, a.s.



14. MARKETING AUTHORISATION NUMBERS

Vm 46608/3007

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{Label-syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nexpraz Duo 18.7 mg/g + 140.3 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	18.7 mg/g
Praziquantel	140.3 mg/g

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 35 days.
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.
Once opened, use by...

7. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the applicator tightly closed. Replace the cap after use.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.



9. BATCH NUMBER

Lot {number}

7.49 g

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nexpraz Duo 18.7 mg/g + 140.3 mg/g Oral Paste for Horses

2. Composition

Each g contains:

Active substances:

Ivermectin	18.7 mg
Praziquantel	140.3 mg

Excipients

Brilliant blue FCF	0.005 mg
Tartrazine	0.021 mg
Titanium dioxide	20.0 mg

Green paste.

3. Target species

Horses

4. Indication(s) for use

For the treatment of mixed cestode and nematode or arthropod infestations caused by adults or immature stages of nematodes, lungworms, botfly larvae and tapeworms in horses.

The veterinary medicinal product is only indicated when use against parasite groups targeted by each of the combined active substances is indicated at the same time.

◆ Nematodes:

Large strongyles:

Strongylus vulgaris (adults and L4 arterial larval stages)

Strongylus edentatus (adults and L4 tissue larval stages)

Strongylus equinus (adults)

Triodontophorus spp. (adults)

Small strongyles:

Cyathostomum spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Gyalocephalus* spp. (adults and uninhibited mucosal larvae)

Parascaris: *Parascaris equorum* (adults and larvae)

Oxyuris: *Oxyuris equi* (larvae)

Trichostrongylus: *Trichostrongylus axei* (adults)

Strongyloides: *Strongyloides westeri* (adults)

Habronema: *Habronema* spp. (adults)

Onchocerca: *Onchocerca* spp., i.e. cutaneous onchocerciasis

Lungworms: *Dictyocaulus arnfieldi* (adults and larvae)

◆ **Cestodes:** *Anoplocephala perfoliata* (adults) **Botflies:** *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. Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each group of animals.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

In the absence of risk of co-infection, a narrow spectrum product should be used.

Partial cross-resistance between ivermectin and moxidectin has been reported. Furthermore, resistance to ivermectin (an avermectin) has been reported in *Parascaris equorum* in horses in a number of countries including the EU. Therefore, the use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.”

Tapeworm infestations are rare in foals before 2 months of age, therefore treatment of foals younger than 2 months of age is not considered necessary.

Confirmed cases of praziquantel resistance in tapeworms infecting horses have been reported in the USA, and the first isolated cases of ivermectin resistance in cythostomins have been reported in the USA from horses imported from the EU. Given the global horse trade, the risk of resistance emerging in Europe is significant.

It is recommended to further investigate suspected resistance cases using an appropriate diagnostic method (e.g., Faecal Egg Count Reduction Test), especially in imported animals or those without a known history of origin.

Tapeworm speciation was not performed in the efficacy study of the veterinary medicinal product. The indication for *A. perfoliata* is based on the typical pathoanatomical finding observed during the efficacy study and its predominant prevalence among equine tapeworms.

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:

People with known hypersensitivity to ivermectin, praziquantel, tartrazine, or cinnamon should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin and eyes.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

In the case of accidental contact with skin or eyes wash the affected area immediately with plenty of water. If skin or eye irritation persist, seek medical advice. In the case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or label to the physician.

Do not eat, drink or smoke while handling the veterinary medicinal product.

Wash hands after use.

Other precautions:

Avermectins may not be well tolerated in all non-target species. Cases of intolerance have been reported in dogs, especially collies, Old English Shepherd dogs and related breeds or their crossbreeds, as well as in turtles and tortoises.

Dogs and cats should not have access to paste residues or used applicators due to the possibility of side effects associated with ivermectin toxicity.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

The veterinary medicinal product can be used safely in stallions.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

A tolerance study performed in foals over 2 weeks of age at 5 times the recommended doses did not show any side effects.

Safety studies performed at 3 times the recommended doses of the veterinary medicinal product in mares at 14-day intervals throughout pregnancy and lactation did not reveal miscarriages, any adverse effects on pregnancy, parturition and general health of the mares, nor any abnormalities on the foals.

Safety studies performed at 3 times the recommended doses of the veterinary medicinal product in stallions did not show any adverse effects, especially on reproductive performance.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horses:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Colic ^{1,3} , Loose Stool ² , Diarrhoea ³ Anorexia ³ Allergic reaction (such as hypersalivation, lingual oedema, urticaria, tachycardia, congested mucous membrane, Allergic oedema)
Undetermined frequency (cannot be estimated from the available data)	Swelling ⁴ Itching ⁴

¹ Mild transient in case of very high levels of infestation, caused by destruction of the parasites

² In case of very high levels of infestation, caused by destruction of the parasites

³ In particular when there is heavy worm burden.

⁴ For horses carrying heavy infection of *Onchocerca microfilariae*. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.

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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system: <{national system information}>.

8. Dosage for each species, route(s) and method of administration

Dosage:

Oral use.

Single administration of 200 µg of ivermectin and 1.5 mg of praziquantel per kg bw, equivalent to 1.07 g of the paste per 100 kg of body weight.

To ensure correct dosing, it is necessary to determine the most accurate weight possible and to measure the appropriate dose to prevent underdosing which may increase the risk of developing anthelmintic resistance.

Horse weight	Paste dose	Horse weight	Paste dose
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 of the applicator of the paste is sufficient to treat animals weighing 100 kg bw.

Each additional division of the applicator will provide a sufficient volume of paste for 50 kg bw. Set the applicator according to the calculated dose by moving the ring to the corresponding mark.

An applicator containing 7.49 g of paste will provide enough paste to treat a horse weighing 700 kg at the recommended dosage.

9. Advice on correct administration

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

Instructions for use:

Before administration, set the applicator according to the calculated dose by moving the ring to the corresponding mark. The paste is administered orally through the interdental space to the root of the tongue. The animal's mouth should not contain any food residue. Immediately after administration, raise the horse's head for a few seconds to ensure that the dose is swallowed properly.

10. Withdrawal periods

Meat and 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.

Store below 25 °C.

Keep the applicator tightly closed. Replace the cap after use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton 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 or household waste.

This veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous to 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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 46608/3007

HDPE multi-dose pre-filled oral syringe with scale printed HDPE piston, PP dosing ring and HDPE cap.

Pack sizes:

Cardboard carton with 1 x 7.49 g oral syringe.

Cardboard carton with 10 x 7.49 g 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 manufacturer responsible for batch release and contact details to report suspected adverse events:

Bioveta, a.s.

Komenského 212/12

683 23 Ivanovice na Hané

Czech Republic

Tel: +420 517 318 911

reklamace@bioveta.cz

Local representatives and contact details for reporting suspected adverse events:

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

17. Other information

Environmental properties:

Ivermectin is very toxic to aquatic organisms and dung fauna and can accumulate in soil and sediment. Like other macrocyclic lactones, ivermectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of ivermectin may take place over a period of several weeks. Faeces containing ivermectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

POM-VPS

Gavin Hall

Approved: 04 March 2026