

EQUIVERM oral paste

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

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIVERM oral paste
(ivermectin/Praziquantel)

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

1 ml of the fine, olive green paste contains:

Active substances:
Ivermectin 20 mg
Praziquantel 100 mg

Excipients:

Butylated hydroxyanisole (E 320) 0.2 mg

4. INDICATIONS

Treatment of infestations with selected types of helminths. Treatment of bots.

The following parasites of horses are sensitive to the antiparasitic effects of EQUIVERM oral paste.

Tapeworm (adults): *Anoplocephala perfoliata*

Large strongyles: *Strongylus vulgaris* (adults and arterial larval stages), *Strongylus edentatus* (adults and tissue larval stages), *Strongylus equinus* (adults).

Tridontophorus spp. (adults), *Tridontophorus brevicauda*, *Tridontophorus serratus*, *Craterostomum acuticaudatum* (adults).

Adults and developmental stages (intraluminal fourth larval stage) of small strongyles or cyathostomes, including strains resistant to benzimidazole: *Coronocylcus* spp., *Coronocylcus coronatus*, *Coronocylcus labiatus*, *Coronocylcus labratus*, *Cyathostomum* spp., *Cyathostomum catinatum*, *Cyathostomum pateratum*, *Cylicocylcus* spp.,

Cylicocylcus ashworthi, *Cylicocylcus elongatus*, *Cylicocylcus insignis*, *Cylicocylcus leptostomum*, *Cylicocylcus nassatus*, *Cylicodontophorus* spp.,

Cylicodontophorus bicornatus, *Cylicostephanus* spp., *Cylicostephanus calicatus*, *Cylicostephanus goldi*, *Cylicostephanus longibursatus*, *Cylicostephanus minutus*, *Parapoteriostomum* spp., *Parapoteriostomum mettami*, *Petrovinema* spp., *Petrovinema poculatum*, *Poteriostomum* spp.

Hairworms (adults): *Trichostrongylus axei*

Pinworms (adults and fourth developmental stage): *Oxyuris equi*

Adults and third and fourth larval stage of roundworms: *Parascaris equorum*

Microfilariae: *Onchocerca* spp.

Intestinal strongyles (adults): *Strongyloides westeri*

Stomach nematodes (adults): *Habronema muscae*

Intestinal and stomach stages of botfly larvae: *Gasterophilus* spp.

Lungworms (adults and fourth developmental stage): *Dictyocaulus arnfieldi*

5. CONTRAINDICATIONS

Do not use in horses hypersensitive to the active substances or to any of the excipients.

Do not use in mares producing milk for human consumption.

The product is intended only for horses. The concentration of ivermectin in the product may have an adverse effect on cats, dogs, especially collies, bobtails and related breeds or crossbreeds, and also on marine and freshwater turtles, if they ingest the product or come into contact with a used applicator.

6. ADVERSE REACTIONS

Some horses heavily infested with *Onchocerca microfilariae* manifested post-treatment oedema and pruritus, probably because of killing of large numbers of microfilariae. These symptoms disappeared within a few days, but symptomatic treatment may be appropriate. In cases of heavy infestations with tapeworms, signs of mild, transient colic and loose stools may appear.

Inflammations of the lips, mouth and tongue have been reported rarely after administration of the drug, which resulted in various clinical symptoms, such as oedema, hypersalivation, erythema, tongue disease, and stomatitis. These reactions, which occur within 1 hour and disappear within 24 to 48 hours, are temporary in nature. If more severe oral reactions occur, it is recommended to proceed to symptomatic treatment.

If you notice any serious side effects or other reactions not listed in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

8. POSOLOGY FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral administration.

The recommended dose is 200 µg of ivermectin and 1 mg of praziquantel per kilogram of animal body weight, which corresponds to a single dose of 1 ml of the paste per 100 kg of animal body weight. The body weight of a horse and dosage should be determined precisely before starting treatment. The contents of one applicator will be sufficient for treatment of a horse weighing up to 700 kg. The applicator is calibrated by 100 kg of weight. The applicator should be adjusted to the calculated dose by setting the ring on a respective piston position.

9. ADVICE ON CORRECT ADMINISTRATION

Hold the piston of applicator, turn the grooved dosing ring on the piston so that the bottom edge of the ring is aligned with the mark of the desired weight. Make sure that the horse has no feed residues in its mouth.

Remove the cap from the applicator, insert it into the interdental space of the horse's mouth and apply the paste to the root of the tongue. After application lift the horse's head immediately for a few seconds and make sure that the horse has swallowed the dose.

Antiparasitic programme

In order to achieve an adequate level of prevention against parasitic infestation, it is necessary to provide veterinary consultancy on appropriate dosing and zoohygienic conditions.

10. WITHDRAWAL PERIOD

Meat: 30 days

Milk: Do not administer to mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.

Store in a tightly closed applicator. After use, replace the cap.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month. Shelf life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Due to increased risk of possible development of resistance, which could lead to ineffective therapy, the administration of the product should be approached cautiously and the following practices should be avoided:
- too frequent and repeated use of anthelmintics from the same group, too long time of administration
- underdosing because of wrong determination of body weight, incorrect administration or inadequate calibration of the dosing device (if used).

Using appropriate tests (e.g. Fecal Egg Count Reduction Test - FECRT), suspected clinical cases should be examined for resistance to anthelmintics. Where test results confirm the resistance to a certain anthelmintic, an anthelmintic belonging to another group and having a different mode of action should be used.

Resistance to macrocyclic lactones (which include ivermectin) was reported in *Parascaris equorum* in horses bred in the EU. Therefore, the use of the product should be based on local (region, farm) epidemiological information about sensitivity of gastrointestinal nematodes and recommendations on how to limit further selection of anthelmintic resistance.

Special precautions for use in animals

There is no study confirming the safety of this product for foals younger than 2 months or stallions, so the product is not recommended for these categories of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The product may cause skin and eye irritation. Avoid contact with skin and eyes. In case of accidental contact with skin or eyes wash the affected area immediately under a stream of clean water. If irritation of the skin or eyes persists, seek medical advice.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to a practitioner.

When handling the veterinary medicinal product (particularly in factory farms), personal protective equipment consisting of protective gloves should be used.

When handling the product, do not eat, drink or smoke. Wash your hands with water and soap after using the product.

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC ORGANISMS. Do not contaminate surface water and sewers with the product or used applicators. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2017

15. OTHER INFORMATION

Studies conducted on laboratory animals showed during the treatment no teratogenic or embryotoxic effect of ivermectin or praziquantel administered at the recommended doses.

The combination of ivermectin and praziquantel can be used after the first three months of pregnancy and during lactation. Due to the absence of clinical data from the period of early pregnancy, the product can be used in the first three months of pregnancy only upon assessment of the risk/benefit ratio by a veterinary doctor.

There were no side effects observed in horses aged 2 months and in adult horses who received up to five and ten times the recommended dose, respectively.

Temporarily decreased appetite, fever, ptialism, and visual changes were observed in horses treated twice with ivermectin oral paste or once with oral paste at doses ten times higher than the recommended dose (i.e. 2 mg/kg of body weight). All changes subsided within five days.

No antidote has been identified, but symptomatic therapy may be beneficial.

For animal treatment only.

Veterinary medicinal product subject to prescription.

Pack size: 1 × 7 ml, 10 × 7 ml

Not all pack sizes may be marketed.

bioveta



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Hanáková

01. 6. 2021

Nakládal

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Kristýna

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