

## EQUISTRONG 400 mg/g oral paste for horses

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

Marketing authorisation holder  
and manufacturer:

Bioveta, a.s.  
Komenského 212  
683 23 Ivanovice na Hané  
Czech Republic

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUISTRONG 400 mg/g oral paste  
for horses  
Pyranteli embonas

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

1 g of the paste contains:

#### Active substance:

Pyranteli embonas

400 mg

#### Excipients:

Butylated hydroxytoluene (E 321) 0.2 mg

Light yellow paste.

### 4. INDICATIONS

Suppression and treatment of infections  
caused by adult small and large  
strongylides, pinworms, roundworms  
and tapeworms in horses.

Pyrantel embonate is a broad-spectrum  
anthelmintic which is efficacious against:  
large strongyles: *Strongylus vulgaris*,  
*S. edentatus*, *S. equinus*

small strongyles: *Trichonema* spp.  
(*Cyathostomes*), *Tridontophorus* spp.

pinworms: *Oxyuris equi*

roundworms: *Parascaris equorum*

tapeworms: *Anoplocephala perfoliata*

### 5. CONTRAINDICATIONS

Do not use in foals younger than  
4 weeks.

Do not use in appreciably debilitated  
animals.

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

### 6. ADVERSE REACTIONS

Pyrantel embonate is safe for horses  
4 weeks age or older, including sucklings,  
pregnant mares and studs.

Small intestine obstruction during the  
treatment may occur in foals infested  
with a large number of roundworms  
(*Parascaris equorum*). Symptoms (colic)  
may appear as early as 30 minutes  
after administration of the product.

If you notice any serious effects or other  
effects not mentioned 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.

One applicator contains 11.4 g  
of pyrantel embonate in 28.5 g of paste.

#### Suppression and treatment of

strongylosis, oxyurosis and parascariosis

Recommended dose is 19 mg of pyrantel  
embonate per kg live weight, or 4.75 g  
of the paste per 100 kg live weight.

One scale division shows the dose  
per 100 kg live weight.

Dosing regimen:

- Foals (1 – 8 months age):  
1 dose (4.75 g of the paste) per 100 kg  
live weight every 4 weeks.

- Horses (more than 8 months age):  
1 dose (4.75 g of the paste) per 100 kg  
live weight every 6 – 8 weeks. Every  
4 – 6 weeks during the grazing season.  
When transferring the horse to grazing  
following winter stabling, always  
administer 1 dose of the paste 3 – 4 days  
before putting the animal out to pasture.

- Nursing mares:

It has been shown that strongyle  
infestation in sucklings during the grazing  
season can be reduced by using "clean"  
pastures (transfer of the horses or not  
grazing down by horses previous year),  
by administering the product to nursing  
mares 3 – 4 days before transfer and  
afterwards repeatedly every 2 – 4 weeks  
till the end of autumn. The ideal pattern is  
to put the mares with the foals out to  
"clean" pastures or, if this is not possible,  
postpone their transfer to June.

#### Suppression and treatment of anoplocephalosis

Recommended dose is 38 mg of pyrantel  
embonate per kg live weight, or 9.5 g  
of the paste per 100 kg live weight.

Two scale divisions show the dose  
per 100 kg live weight.

Repeat application in 6 weeks  
if necessary.

### 9. INSTRUCTIONS FOR PROPER ADMINISTRATION

The weight of the animal must be  
determined as accurately as possible  
prior to starting the treatment.

Set the applicator by adjusting the ring  
to the mark on the piston so as to match  
the calculated dose.

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  
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.

### 10. WITHDRAWAL PERIOD

Do not use in horses whose milk and/or  
meat is intended for human consumption.

### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight  
of children.

This veterinary medicinal product  
does not require any special storage  
conditions.

Store in a dry place.

Do not use after expiry date indicated  
on the label and carton.

Shelf life after first opening the container:  
6 months.

### 12. SPECIAL WARNINGS

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 incorrect  
setting of the dosing device.

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 pyrantel has been reported  
for equine cyathostomes (widespread  
in the US and Canada). The use of this  
product should thus be based on local  
epidemiological information regarding  
sensitivity of the nematode species  
and recommendation on how to limit  
additional selection of resistance  
to anthelmintics.

Dimensions (mm):

Colours:

Prepared by:

Date:

A5 (148 × 210 mm) duplex printing

black

Vlková

22. 9. 2016

Approved by:

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Date:

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**Special precautions for use in animals**

The same applicator should be used on two different animals only if both animals are healthy and in a common paddock or in a common space and in direct contact.

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

When using do not eat, drink or smoke.

Wash your hands with water and soap after using the product.

The product may cause skin and eye irritation. Avoid contact with skin and eyes. In case of accidental spillage onto skin wash the affected area immediately with soap and plenty of water.

In case of accidental eye contact rinse eyes immediately with running pure water.

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

People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

Pregnant women should administer this product with caution.

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

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**

March 2016.

**15. OTHER INFORMATION****Mode of action:**

Pyrantel embonate is a wide-spectrum anthelmintic belonging to the group of tetrahydropyrimidine anthelmintics. The mechanism of action of pyrantel rests in induction of spastic paralysis.

Pyrantel is a cholinergic agonist which acts as an excitatory neurotransmitter on nicotinic receptors in the parasite's muscle cells. The bonding to the receptors brings about depolarization of the neuromuscular junctions, resulting in muscle contraction (the conditions is similar to the contraction on the action of acetylcholine) or even spastic paralysis. The parasite does not die on the action of pyrantel: it is eliminated from the host body live.

Pyrantel embonate has a broad spectrum of action, including activity against important endoparasites of horses, such as large and small strongylides, pinworms, house roundworm and tapeworm.

**Interaction**

Do not administer concomitantly with products containing levamisole or piperazine, which can affect the pharmacodynamic effect of pyrantel.

Concomitant administration with diethylcarbamazine and organophosphates is not recommended because of enhanced risk of adverse effects.

**Overdose**

Pyrantel embonate is a substance with well-known low toxicity after oral administration.

Laboratory studies have shown that twenty times the standard dose (i.e. up to 60 mg of the active substance per kg live weight) has no adverse effects in horses or in foals.

For animal treatment only.

To be supplied only on veterinary prescription.

Pack size: 1 × 28.5 g, 10 × 28.5 g.

Not all pack sizes may be marketed.

**bioveta**

