B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Helminthex 425 mg/g oral paste for horses

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

Marketing authorisation holder:
Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

Manufacturer responsible for batch release:
Produlab Pharma BV
Forellenweg 16
4941 Raamsdonksveer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Helminthex 425 mg/g oral paste for horses (AT, CZ, IT, LV, PL, PT)
Helminthex oral paste for horses (FR)

Pyrantel embonate

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

1 g of paste contains:

Active substance:
Pyrantel embonate 425.45 mg (equivalent to 147.6 mg pyrantel)

Excipients:
Sodium methyl parahydroxybenzoate(E 219) 2.5 mg
Sodium propyl parahydroxybenzoate 1.5 mg

Yellow oral paste.

4. INDICATION(S)

Treatment of infections with adult intestinal stages of large strongyles (*S.vulgaris, S. edentatus, S.equinus*), small strongyles (*Triodontophorus spp., Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp.*,), pinworms (*Oxyuris equi*) and large horse roundworm (*Parascaris equorum*).

5. CONTRAINDICATIONS

Do not use in severely debilitated animals.

6. ADVERSE REACTIONS

In animals that are suffering from severe endoparasite infestation associated with lesions of the intestinal mucosa, absorption of pyrantel might be increased. Symptoms like muscle tremor, increased salivation, tachypnoe, diarrhoea and decreased activity of cholinesterase may occur very rare.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

Alternatively you can report via your national reporting system {national system details

7. TARGET SPECIES

Horses

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

For oral use.

19.5 mg pyrantel embonate/kg bw once, corresponding to 1 entire 27.5 g applicator of Helminthex for a 600 kg horse or 1 entire 32.08 g applicator for a 700 kg horse.

To ensure a correct dosage, body weight should be determined as accurately as possible.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

The individual dose is ensured by turning the lock ring until the ring lines up with estimated body weight of the animal to be treated. Each graduation of the syringe allows the treatment of 50 kg of bodyweight. Place the applicator in the animal's mouth and expel the required dose on the back of the tongue. Take care that the intended dose is administered completely. Raising the horses head may in some case facilitate the swallowing process.
Foals should be treated initially at the age of 8 weeks.
Dosing programmes should be adjusted according to national or regional recommendations based on the local epidemiological conditions. For control programmes the egg reappearance period should be taken into consideration.
Replace cap after use

9. ADVICE ON CORRECT ADMINISTRATION

[Not applicable]

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 day.
Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Care should be taken to avoid the following practices as this may increase the risk of resistance development and could ultimately result in ineffective therapy:

Too frequent and repeated use of anthelmintics from the same class over an extended period. Underdosing, which may be due to underestimation of bodyweight or incorrect administration of the product.

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.

For small strongyles in horses resistance towards pyrantel has occasionally been reported from different countries including member states of the EU. The use of the product on local/ national level therefore should be based on epidemiological information and professional recommendation to limit further selection of resistance to anthelmintics.

Special precautions for use in animals:
The same applicator should only be used in animals of the same herd and which have direct contact with each other.
In order to avoid direct release of pyrantel to the environment, horses should not be turned out onto pasture within 3 days of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to pyrantel or any excipients should avoid contact with the veterinary medicinal product.
Avoid direct contact with skin, mucosa or eyes.
In case of contact with skin, mucous membranes or eyes, rinse intensively with water.
Do not smoke, eat or drink when handling the product.
Wash hands after use.

Other precautions regarding impact on the environment:
In order to avoid direct release of pyrantel to the environment, horses should not be turned out onto pasture within 3 days of treatment.

Pregnancy and lactation:
The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Pyrantel should not be used concomitantly with other parasympathomimetics (e.g levamisole) or inhibitors of cholinesterase (e.g organophosphate). Specific activities of piperazine may block the effects of pyrantel (spastic paralysis of the parasites).

Overdose (symptoms, emergency procedures, antidotes):
The product is well tolerated up to 6 times of the recommended therapeutic dose for nematodes (117 mg/kg bw). In case of signs of overdosage atropine can be used as antidote.

Incompatibilities:
None known.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:
1, 10 or 20 applicators containing 27.5 g of paste
1, 10 or 20 applicators containing 32.08 g of paste

Not all pack sizes may be marketed.