

CANIVERM forte tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE PRODUCTION AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF NOT IDENTICAL

Marketing authorization holder and producer responsible for batch release:

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

2. NAME OF THE MEDICINAL PRODUCT CANIVERM forte tablets

Fenbendazolum, pyranteli embonas,
praziquantelum

3. CONTENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet weighing 0.7 g contains:

Active substance(s):	
Fenbendazolum	150 mg
Pyranteli embonas	144 mg
Praziquantelum	50 mg

Oval, yellowish biconvex tablets with small spots and a central dividing line on both sides.

4. INDICATIONS

Diseases caused by nematodes and tapeworms of dogs, cats, feline and canine beasts. (*Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*, *Trichuris vulpis*, *Echinococcus granulosus*, *Echinococcus multilocularis*, *Dipylidium caninum*, *Taenia* spp., *Multiceps multiceps*, *Mesocestoides* spp.).

5. CONTRAINDICATIONS

Ocular cysticercosis and spinal neurocysticercosis. Liver damage. Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Vomiting, mushy stool, urticaria or fever may occur within a few hours after administration. It is the reaction to released proteins from the dying parasites, it is not any reaction to the drug. The medicinal product may cause drowsiness of the animal.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, or if you think that the medicinal product does not work / is not effective, tell it to your veterinary surgeon, please.

7. TARGET SPECIES OF ANIMALS

Dogs, cats. Feline and canine beasts.

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

Single oral administration.

Dosage:

It is recommended to deworm the pups from the 3rd to 12th week of age as a single dose, in the interval of 3 weeks, and then regularly every 3 months.

Puppies, small breeds of dogs and cats:

- 1/2 tablet 0.7 g per 2 - 5 kg b.w.

Medium breeds of dogs:

- 1 tablet 0.7 g per 5 - 10 kg b.w.

Large breeds of dogs and large beasts:

- 1 tablet 0.7 g per each started 10 kg b.w.

9. INSTRUCTIONS FOR CORRECT ADMINISTRATION

The tablets can be given alone or wrapped in a piece of food. Do not administer simultaneously with the dairy food.

For the beasts (feline, canine) in zoos, circuses, etc., it is recommended to mix the crushed tablets according to the weight of the beast into a meatball and distribute them in the paddock according to the number of animals before the morning feeding.

Avoid underdosage due to incorrect determination of the body weight or incorrect administration of the drug.

10. WITHDRAWAL PERIOD(S)

Not intended for food-producing animals.

11. SPECIAL STORAGE CONDITIONS

Keep out of sight and reach of children.

Do not store above 25 °C.

Store in a dry place.

Protect from light.

Do not use after the date of expiry which is shown on the carton and blister or strip after EXP.

12. SPECIAL WARNINGS

Special warnings

Possible side effects have to be discussed with a veterinarian.

The medicinal product may not be applied to animals that show symptoms of the disease other than intestinal parasitic disease.

Resistance of parasites to any group of anthelmintics may develop after frequent, repeated use of anthelmintics from the same group.

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

People with known hypersensitivity to praziquantel, pyrantel embonate, fenbendazole or excipients should not come into contact with this medicinal product for veterinary use.

Avoid contact with eyes, including hand-to-eye contact when handling the medicinal product. In case of direct contact with eyes, rinse the eyes immediately with plenty of water.

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

Wash hands after use.

Echinococcosis poses a risk to humans.

As echinococcosis is the disease subject to reporting to the World Organization for Animal Health (OIE), specific instructions for treatment, the follow-up procedure and instructions for protection of persons have to be obtained from the competent authority.

Pregnancy

In pregnant bitches, the dosage should be followed exactly.

Interaction with other medicinal products and other forms of interaction

Do not administer at the same time with piperazine-based medicinal products and/or with other antiparasitic agents.

Overdose (symptoms, first aid procedures, antidotes)

The 10-fold increase in dose does not have any side effects on the target species of animals.

Incompatibilities

N/A.

13. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused medicinal product for veterinary use or waste materials arisen from this medicinal product for veterinary use has to be disposed in accordance with the local legal regulations.

14. DATE OF THE LAST REVISION OF THE PACKAGE INSERT

September 2020

15. FURTHER INFORMATION

For animals only.

Pack sizes: 2 tablets, 6 tablets, 100 tablets
Not all pack sizes can be marketed.

Applies to packs with 2 tablets and 6 tablets:
The medicinal product for veterinary use is available without prescription.

Applies to the packs with 100 tablet:
The medicinal product for veterinary use is on prescription only.



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Hanáková

10. 5. 2021

Approved by:

Date: