

PACKAGE LEAFLET
GALCES PLUS, tablets for dogs

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

PHARMAGAL, s.r.o., Murgašova 5, 949 01 Nitra, Slovak Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALCES PLUS, tablets for dogs

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

Round yellowish tablets with a score line. Tablets can be divided into equal halves.

1 tablet contains:

Active substances:

Febantel	150.0 mg
Pyrantel embonate	144.0 mg (corresponding to 50 mg Pyrantel)
Praziquantel	50.0 mg

4. INDICATIONS

Nematodosis and cestodosis in dogs caused by *Toxascaris leonina*, *Toxocara canis* (adult and late immature forms), *Ancylostoma caninum*, *Uncinaria stenocephala*, *Trichuris vulpis* (adult), *Echinococcus granulosus*, *Echinococcus multilocularis*, *Taenia* spp. and *Dipylidium caninum* (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds.

6. ADVERSE REACTIONS

No adverse reactions were reported.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For single oral use only.

The recommended dose rates are: 15 mg Febantel, 14,4 mg Pyrantel embonate and 5 mg Praziquantel per 1 kg b. w., i.e. 1 tablet per 10 kg b. w. .

Puppies and small dogs:

¼ tablet per 0.5-2 kg b.w.,

½ tablet per more than 2 kg to 5 kg b.w.,

1 tablet per more than 5 kg to 10 kg b.w..

Medium and large dogs:

2 tablets per more than 10 kg to 20 kg b.w.,

3 tablets per more than 20 kg to 30 kg b.w.,

4 tablets per more than 30 kg to 40 kg b.w

Tablets can be applied either directly to dogs by placing them on root of the tongue or by disguising them in the favourite food.

No starvation is needed before or after the treatment.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age.

It is advisable to treat the bitch at the same time as the puppies.

Regular worming of dogs should be carried out every three months on the basis of the coprological examination.

In the event of heavy roundworm infestation a repeat dose should be given after 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25°C.

Protect from light.

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

12. SPECIAL WARNINGS

Special warnings for each target species:

The resistance of the parasites against any of the anthelmintics class can develop after frequent and repeated use of the anthelmintics from the same class.

Special precautions for use in animals

The dietary measures are not necessary to be kept in puppies and adult dogs.

Fleas serve as intermediate hosts of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas is undertaken.

Avoid the under-dosing due to underestimation of body weight or misadministration of the product.

Consult a veterinary surgeon before treating pregnant animals for roundworms.

Do not exceed the stated dose when treating pregnant bitches.

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

- Wash your hands after use.
- In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
- People with known sensitivity to any component of the product should avoid contact with the veterinary medicinal product.

Pregnancy:

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine products and organophosphate ectoparasitics.

Overdose (symptoms, emergency procedures, antidotes):

GALCES PLUS is well tolerated in dogs. The veterinary product has a wide safety margin, beyond three- and five-times overdose

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size:

1 blister of 4 tablets (4 tablets)

1 blister of 10 tablets (10 tablets)

5 blisters of 10 tablets (50 tablets)

10 blisters of 10 tablets (100 tablets)

Not all pack sizes may be marketed.

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