SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALCES PLUS, tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

Active substances:

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

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

4.CLINICAL PARTICULARS

4.1. Target species

Dogs

4.2. Indications for use, specigying the target species

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).*

4.3. Contraindications

Do not use simultaneously with piperazine compounds.

4.4. 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.

4.5. Special precautions for use

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.

4.6. Adverse reactions (frequency and seriousness)

No adverse reactions were reported.

4.7. Use during pregnancy, lactation and lay

Pregnancy:

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

4.8. Interaction with other medicinal products and other forms of interactions

Do not use simultaneously with piperazine products and organophosphate ectoparasitics.

4.9. Amounts to be administered and administration route

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.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11. Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Benzimidazoles and related substances
ATCvet code: QP52AC55

5.1. Pharmacodynamic properties

In this fixed combination, Pyrantel and Febantel act synergically against all relevant nematodes in dogs – *Toxocara canis, Toxascaris leonina, Uncinaria stenocephala, Ancylostoma caninum* and *Trichuris vulpis.*

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia spp., Dipylidium caninum Echinococcus granulosus* and *Echinococcus multilocularis.* Praziquantel acts against all adult and immature forms of these parasites.

Febantel – pro-benzimidazole on its own is not effective in organism. It metabolises into Fenbendazole, Oxfendazole and Oxfendazolsulfone. Those metabolities have anthelmintic effect. This anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

Pyrantel embonate - embonate salt of tetrahydropyrimidine acting as a cholinergic agonist, which induces the paralysis of nerve impulses in roundworms.

Praziquantel – is a cholinesterase agent which paralyses the transfer of nerve impulses in tapeworms.

5.2. Pharmacokinetic particulars

Febantel – is poorly absorbed from gastrointestinal tract after oral administration to dogs. It is rapidly metabolized in liver to Fenbendazol and its hydroxy- and oxidative derivates as Oxfendazol. Maximum plasma concentration of Fenbendazol is achieved after 5 hours. Maximum plasma concentration of Oxfendazol is achieved after 7 hours. Metabolites of febantel are eliminated via faeces.

Pyrantel embonate – is slightly absorbed after oral administration. Maximum plasma concentration is achieved after 2 hours. It is rapidly and significantly metabolized in liver and is rapidly eliminated via faeces (in unchanged form) and via urine (metabolites).

Praziquantel – is rapidly and significantly absorbed from gastrointestinal tract after oral administration to dogs. Maximum plasma concentration is achieved up to 2 hours. It is rapidly and significantly metabolized in liver into 4-hydroxycyklohexylated-derivate. In dogs, 60-80% of dose is eliminated via urine and the rest via bile into faeces.

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K 30
Sodium lauril sulfate
Magnesium stearate
Colloidal silicon dioxide

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packed for sale: 3 years.

6.4. Special precautions for storage

Store below 25°C.

Protect from light.

6.5. Nature and composition of immediate packaging

PVC blister with printed aluminium foil:

Outer packaging: paper box.

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.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORIZATION HOLDER

PHARMAGAL, s.r.o., Murgašova 5, 949 01, Nitra, Slovak Republic
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8. MARKETING AUTHORIZATION NUMBER(S)

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

10. DATE OF REVISION OF THE TEXT