

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{NATURE/TYPE} Paper box 4 tablets, 10 tablets., 5 x 10 tablets, 10 x 10 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALCES PLUS, tablets for dogs

Picture of the dog was used.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:

Active substances:

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

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

4 tablets

10 tablets

50 tablets

100 tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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).

Selected pictograms of the target worms were used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For single oral use only.

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

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.

8. WITHDRAWAL PERIOD

Withdrawal period:

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

During pregnancy, use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25°C.

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTION REGARDING SUPPLY AND USE, IF APPLICABLE

Cz: For animal treatment only.

PL: For animal treatment only – To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

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

A discreet logo of the MAH was used.

16. MARKETING AUTHORIZATION NUMBER(S)
--

17. MANUFACTURER'S BATCH NUMBER
--

Batch:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE} **blister 4 x 1 tbl., blister 10 x 1 tbl.**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALCES PLUS, tablets for dogs

2. NAME OF THE MARKETING AUTHORIZATION HOLDER

PHARMAGAL

A discreet logo of the MAH was used.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.