

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2,4, 6 AND 8 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm Tablets for Dogs 50/50/150 mg
Praziquantel, Pyrantel, Febantel

2. STATEMENT OF ACTIVE SUBSTANCES

50 mg/tablet Praziquantel, 50 mg/tablet Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

2, 4, 6, 8 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Single dose: For oral administration.

1 tablet per 10 kg bodyweight.

The tablet can be divided in two or four equal doses.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Discard any unused divided tablets immediately.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.

This veterinary medicinal product does not require any special storage conditions

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

Please refer to package leaflet for disposal advice.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

NFA-VPS

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 AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4069

17. MANUFACTURER'S BATCH NUMBER

BN{number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 10 TABLETS, AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm Tablets for Dogs
50/50/150 mg
Praziquantel, Pyrantel, Febantel

2. STATEMENT OF ACTIVE SUBSTANCES

50 mg/tablet Praziquantel, 50 mg/tablet Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species

Nematodes:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

Cestodes:

Tapeworms: *Echinococcus* species, (*E. granulosus*, *E. multilocularis*), *Taenia* species,

(*T. hydatigena*, *T. pisiformis*, *T. taeniformis*) *Dipylidium caninum* (adult and immature forms).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single dose: For oral administration.

To ensure administration of a correct dose, body weight should be determined as accurately as possible

Read the package leaflet before use.

1 tablet per 10kg (22lbs) bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

The tablet can be divided in two or four equal doses.

Dosage table:

Bodyweight (kg)	Tablets
½ - 2.5	1/4
2.6-5.0	½
5.1-10.0	1
10.1-15.0	1½
15.1-20.0	2
20.1-25.0	2½
25.1-30.0	3
30.1-35.0	3½
35.1-40.0	4
>40.1	1 tablet per 10 kg

The advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Discard any unused divided tablets immediately.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.

This veterinary medicinal product does not require any special storage conditions

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

Please refer to package leaflet for disposal advice.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

NFA-VPS

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 AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4069

17. MANUFACTURER’S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm Tablets for Dogs
50/50/150 mg
Praziquantel, Pyrantel, Febantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

PACKAGE LEAFLET
TermaWorm Tablets for Dogs
50/50/150 mg

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

Marketing authorisation holder and manufacturer for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm Tablets for Dogs 50/50/150 mg
Praziquantel, Pyrantel, Febantel

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

Pale yellow pork-flavoured tablets with a cross breakline on one side . Each tablet contains Praziquantel 50 mg, Pyrantel 50 mg (equivalent to 144 mg Pyrantel Embonate and Febantel 150 mg. The tablets can be divided into halves or quarters.

4. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species

Nematodes:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

Cestodes:

Tapeworms: *Echinococcus* species, (*E. granulosus*, *E. multilocularis*), *Taenia* species,

(*T. hydatigena*, *T. pisiformis*, *T. taeniformis*) *Dipylidium caninum* (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

6. ADVERSE REACTIONS

Slight and transient digestive tract disorders such as vomiting and /or diarrhoea may occur in very rare spontaneous reports. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

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.

7. TARGET SPECIES

Dogs

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

Single dose: For oral administration.

The recommended dose rates are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel.

1 tablet per 10 kg (22 lbs) bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

The tablet can be divided in two or four equal doses.

Dosage table:

Bodyweight (kg)	Tablets
½ - 2.5	1/4
2.6-5.0	½
5.1-10.0	1
10.1-15.0	1½
15.1-20.0	2
20.1-25.0	2½
25.1-30.0	3
30.1-35.0	3½
35.1-40.0	4
>40.1	1 tablet per 10 kg

The advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

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.

This veterinary medicinal product does not require any special storage conditions
Keep out of the sight and reach of children.

Discard any unused divided tablets immediately.

12. SPECIAL WARNING(S)

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Concurrent use with other cholinergic compounds (e.g.foxim) can lead to toxicity.

If you are uncertain, and your dog uses other veterinary medicinal products,check with a veterinary surgeon or pharmacist.

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Tapeworm infestation is unlikely in pups less than 6 weeks of age.

Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

User Precautions:

In case of accidental ingestion, seek medical advice and show the package leaflet to the physician. In the interests of good hygiene, persons administering the tablets directly to a dog or adding them to the dog's food should wash their hands afterwards.

Other Precautions:

Echinococcosis represents a hazard for humans. As echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Overdose:

The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.

Not all pack sizes may be marketed.

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Approved: 16/06/21

