<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2,4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 AND 44 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm XL Tablets for Dogs
175/175/525 mg
Praziquantel, Pyrantel, Febantel,

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel (equivalent to 504 mg pyrantel embonate) and 525 mg Febantel.

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 or 44 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

For oral administration.
1 tablet per 35 kg bodyweight.
Read the package leaflet before use

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Unused half tablet must be used within 14 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions
Do not use after expiry date.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton. Keep the blister in the outer carton.

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

C&H Generics Limited
c/o Michael Mc Evoy and Co
Seville House
New Dock Street
Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4019

17. MANUFACTURER'S BATCH NUMBER

BN{number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 48 TABLETS, AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm XL Tablets for Dogs
175/175/525 mg
Praziquantel, Pyrantel, Febantel.

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel (equivalent to 504 mg pyrantel embonate) and 525 mg Febantel.

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In adult 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

For oral administration.

Read the package leaflet before use.
To ensure administration of a correct dose, body weight should be determined as

accurately as possible.
1 tablet per 35kg bodyweight. Dogs of > 35 kg bodyweight should be given 1 TermaWorm XL Tablets for Dogs plus the appropriate quantity of TermaWorm Dog Tablets equivalent to 1 tablet per 10 kg bodyweight.

Dogs weighing approx 17.5kg bodyweight should be given ½ TermaWorm XL tablet. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

Dosage table:

Bodyweight (kg)	**Tablets**
Approx 17.5kg	½ TermaWorm XL Tablets for Dogs
31-35 kg	1 TermaWorm XL Tablets for Dogs
36-40 kg	1 TermaWorm XL Tablets for Dogs ½ TermaWorm Dog Tablets
41-45 kg	1 TermaWorm XL Tablets for Dogs 1 TermaWorm Dog Tablets
46-50 kg	1 TermaWorm XL Tablets for Dogs 1½ TermaWorm Dog Tablets
51-55 kg	1 TermaWorm XL Tablets for Dogs 2 TermaWorm Dog Tablets
56-60 kg	1 TermaWorm XL Tablets for Dogs 2½ TermaWorm Dog Tablets
61-65 kg	1 TermaWorm XL Tablets for Dogs 3 TermaWorm Dog Tablets
66-70 kg	2 TermaWorm XL Tablets for Dogs

If there is a risk for re-infestation, 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}
Unused half tablet must be used within 14 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Do not use after expiry date.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton. Keep the blister in the outer carton.

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

C&H Generics Limited
c/o Michael Mc Evoy and Co
Seville House
New Dock Street
Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4019

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 XL Tablets for Dogs
175/175/525 mg
Praziquantel, Pyrantel, Febantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Limited

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 XL Tablets for Dogs
175/175/525 mg

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

Marketing Authorisation Holder
C&H Generics Limited
c/o Michael Mc Evoy and Co
Seville House
New Dock Street
Galway
Ireland

Manufacturer Responsible for Batch Release
Chanelle Pharmaceuticals Manufacturing Ltd
Dublin Road
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaWorm XL Tablets for Dogs
175/175/525 mg
Praziquantel, Pyrantel, Febantel

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

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel (equivalent to 504 mg pyrantel embonate) and 525 mg Febantel. The tablets can be divided into halves.

A yellow coloured oblong tablet with a breakline on both sides.

4. INDICATION(S)

In adult 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 cases. Nonspecific signs such as lethargy, anorexia or hyperactivity can accompany these signs in individual cases.

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

For oral administration.
The recommended dose rates are: 15mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 TermaWorm XL Tablets for Dogs per 35 kg bodyweight.
Dogs of > 35 kg bodyweight should be given 1 TermaWorm XL Tablets for Dogs plus the appropriate quantity of TermaWorm Dog Tablets equivalent to 1 tablet per 10 kg bodyweight.
Dogs weighing approx 17.5kg bodyweight should be given ½ TermaWorm XL tablet.
The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

Dosage table:

Bodyweight (kg)	**Tablets**
Approx 17.5kg	½ TermaWorm XL Tablets for Dogs
31-35 kg	1 TermaWorm XL Tablets for Dogs
36-40 kg	1 TermaWorm XL Tablets for Dogs ½ TermaWorm Dog Tablets
41-45 kg	1 TermaWorm XL Tablets for Dogs 1 TermaWorm Dog Tablets
46-50 kg	1 TermaWorm XL Tablets for Dogs 1½ TermaWorm Dog Tablets
51-55 kg	1 TermaWorm XL Tablets for Dogs 175/504/525 mg 2 TermaWorm Dog Tablets
56-60 kg	1 TermaWorm XL Tablets for Dogs 175/504/525 mg 2½ TermaWorm Dog Tablets
61-65 kg	1 TermaWorm XL Tablets for Dogs 3 TermaWorm Dog Tablets
66-70 kg	2 TermaWorm XL Tablets for Dogs

If there is a risk for re-infestation, 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

Keep out of the sight and reach of children
This veterinary medicinal product does not require any special storage conditions
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.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton. Keep the blister in the outer carton.
Unused half tablet must be used within 14 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Special precautions for use in animals:
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.

Pregnancy:
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.

Overdose (symptoms, emergency procedures, antidotes):
In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting

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.
For animal treatment only.

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.

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

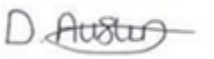
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Approved: 16/06/21