1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exitel Plus XL Tablets For Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substances:

Praziquantel	175 mg
Pyrantel Embonate	504 mg (equivalent to 175 mg pyrantel)
Febantel	525 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate,
Microcrystalline cellulose,
Magnesium stearate,
Colloidal anhydrous silica,
Croscarmellose sodium,
Sodium laurilsulfate
Pork flavour

A yellow coloured oblong tablet with a breakline on both sides.
The tablets can be divided into two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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).

3.3 Contraindications

Do not use simultaneously with piperazine compounds.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm – Dipylidium caninum. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product."

3.5 Special precautions for use

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
In the interests of good hygiene, persons administering the tablets directly to the dog, or by adding them to the dog's food, should wash their hands afterwards

Special precautions for the protection of the environment:
Not applicable.

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.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (diarrhoea, emesis)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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. The use is not recommended during the first 4 weeks of pregnancy in dogs. Do not exceed the stated dose when treating pregnant bitches.

3.8 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 antagonised.
Concurrent use with other cholinergic compounds can lead to toxicity.

3.9 Administration routes and dosage

Oral Use.

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. This is equivalent to 1 Exitel Plus XL tablet per 35 kg. bodyweight.
Dogs weighing approximately 17.5 kg. bodyweight should be given ½ Prazitel Plus XL tablet.
Dogs of > 35 kg. bodyweight should be given 1 Exitel Plus XL tablet plus the appropriate quantity of Exitel Plus tablets equivalent to 1 tablet per 10 kg. bodyweight.
The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.
The tablets can be divided into two equal parts.

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.
To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AA51

4.2 Pharmacodynamics

This Veterinary medicinal product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The veterinary medicinal product contains three active substances, as follows:

1. Febantel, a probenzimidazole

2. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative

3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

In this fixed combination, pyrantel and febantel act against all relevant nematodes (ascarids, hookworms, and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*.

This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. 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.

Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Both in vitro and in vivo studies have shown that praziquantel causes severe damage to the parasite integument, resulting in the contraction and paralysis of the parasites. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis of the nematodes and thereby allow removal from the gastrointestinal system by peristalsis.

Within the mammalian system, febantel undergoes ring closure, forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later.

4.3 Pharmacokinetics

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolised into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.

Following administration of the veterinary medicinal product to dogs, peak plasma concentrations of praziquantel were achieved by approximately 2.5 hours.

The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine.

Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.
Febantel is absorbed relatively rapidly and metabolised to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.
Following administration of the veterinary medicinal product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 7-9 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not Applicable

5.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life of half tablets: 14 days .

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The product is presented in:
Blister packs made up of PVC/PE/PCTFE with 20µ hard tempered aluminium foil with 2, 4, 5, 6, 8, 10, 12, 14, 16, 18 or 20 tablets per blister.

The Blisters are packed into cartons containing either 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.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/078/002

8. DATE OF FIRST AUTHORISATION

02/03/2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21/08/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<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 ,44, 48 TABLETS, AND UPWARDS }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exitel Plus XL Tablets For Dogs (AT, EE, EL,IE, NL, RO)
Exitel XL Tablets For Dogs (DE)
Frontcontrol wormer compresse per cani di taglia grande(IT)
Strantel Plus XL Tablets for Dogs (UK)
Frontcontrol wormer tablet for dogs (HU, SK, SI, CZ)
FRONTCONTROL VET XL Tabletit Koiralle (FI)
FRONTCONTROL VET XL tablet for hund (SE)
Exitel XL comprimés pour chiens (FR)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg Pyrantel) and 525 mg Febantel .

3. PACKAGE SIZE

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

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

4. TARGET SPECIES

Dogs.

5. INDICATIONS

For products not subject to veterinary prescription.
Treatment of mixed infections by nematodes and cestodes.

6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet per 35 kg bodyweight.
The tablets can be given directly to the dog or disguised in food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life of half tablets: 14 days

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

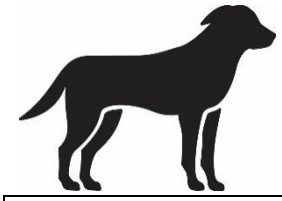
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exitel Plus XL (AT, EE, EL, IE, NL, RO)
Exitel XL (DE, FR)
Frontcontrol wormer (IT, HU, SK, SI, CZ)
Frontcontrol Vet XL (FI, SE)
Strantel Plus XL (UK)



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg Pyrantel) and 525 mg Febantel.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Exitel Plus XL Tablets For Dogs (AT, EE, EL,IE, NL, RO)
Exitel XL Tablets For Dogs (DE)
Frontcontrol wormer compresse per cani di taglia grande (IT)
Strantel Plus XL Tablets for Dogs (UK)
Frontcontrol wormer tablet for dogs (HU, SK, SI, CZ)
FRONTCONTROL VET XL Tabletit Koiralle (FI)
FRONTCONTROL VET XL tablet for hund (SE)
Exitel XL comprimés pour chiens (FR)

2. Composition

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

A yellow coloured oblong tablet with a breakline on both sides.
The tablets can be divided into two equal parts.

3. Target species

Dogs

4. Indications for use

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 cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special Warnings:
Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice and show the package leaflet or the label 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.

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. The use is not recommended during the first 4 weeks of pregnancy in dogs. Do not exceed the stated dose when treating pregnant bitches.

Interactions 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.

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.

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.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (diarrhoea, emesis)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

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. This is equivalent to 1 Exitel Plus XL tablet per 35 kg. bodyweight.
Dogs of > 35 kg. bodyweight should be given 1 Exitel Plus XL tablet plus the appropriate quantity of Exitel Plus tablets equivalent to 1 tablet per 10 kg. bodyweight.
Dogs weighing approximately17.5 kg. bodyweight should be given ½ Exitel Plus 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**
Approximately 17.5 kg.	½ Exitel Plus XL tablet
31-35 kg.	1 Exitel Plus XL tablet
36-40 kg.	1 Exitel Plus XL tablet plus ½ Exitel Plus tablet
41-45 kg.	1 Exitel Plus XL tablet plus 1 Exitel Plus tablet
46-50 kg.	1 Exitel Plus XL tablet plus 1½ Exitel Plus tablets

51-55 kg.	1 Exitel Plus XL tablet plus 2 Exitel Plus tablets
56-60 kg.	1 Exitel Plus XL tablet plus 2½ Exitel Plus tablets
61-65 kg.	1 Exitel Plus XL tablet plus 3 Exitel Plus tablets
66-70 kg.	2 Exitel Plus XL tablets

The tablets can be divided into two equal parts
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. Advise on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Not Applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf-life of half tablets: 14 days.
Each time an unused half tablet is stored, it should be returned to the open blister space and the blister inserted back into the outer carton.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

BG, HU, IE, IT, LV, LT, NL, SK, UK, HU, SI, FI, CZ: Veterinary medicinal product not subject to prescription.

AT, DK, DE, EL, LU, PL, PT, IS, ES: Veterinary medicinal product subject to prescription.

SE, FR: Veterinary medicinal product subject to veterinary prescription except for some pack sizes.

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database.
https://upd-portal-prod.azurewebsites.net/updwebui/home

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

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