

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exitel Plus Tablets For Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Active substances:

Praziquantel	50 mg
Pyrantel	50 mg (equivalent to 144 mg pyrantel embonate)
Febantel	150 mg

3. PHARMACEUTICAL FORM

Tablet

A pale yellow tablet with a cross breakline on one side.

The tablets can be divided into equal halves or equal quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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).

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

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

4.4 Special warnings for each target species

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.

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

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

4.5 Special precautions for use

Special precautions for use in animals

None.

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 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.

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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, gastrointestinal disorders (diarrhoea, emesis) have been observed.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 antagonized.

Concurrent use with other cholinergic compounds can lead to toxicity.

4.9 Amounts to be administered and administration route

Single dose: For oral administration only.

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

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

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

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.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, praziquantel combinations.
ATC vet code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The 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 *Trichouris 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 vacuolization 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.

5.2 Pharmacokinetic particulars

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized 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 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 metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity". Following administration of the product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 7-9 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Not applicable

6.2 Shelf life of the veterinary medicinal product as packaged for sale

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Discard any unused divided tablets immediately.

6.3. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.4 Nature and composition of immediate packaging

The product is presented in either:

Individual strips composed of aluminium foil 30 µm/30 gsm extruded polythene, containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.

or

Individual blisters composed of 45 µm, soft temper aluminium foil and 25 µm hard temper aluminium foil, containing 2 or 8 tablets.

The strips or blisters are packed into cartons containing either 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 or 1000 tablets.

Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBER(S)

VPA 10987/078/001

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<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

Exitel Plus Tablets For Dogs.

Easimax Plus Tablets For Dogs. (UK),Exitel Tablets For Dogs (Germany, Norway, Spain).

Exitel Plus (Denmark)

Exitel vet.150 mg/144 mg/50 mg Tablets for dogs (Sweden)

Praziquantel, Febantel, Pyrantel.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Pork flavoured tablets.

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.

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(S)

VPA 10987/078/001

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

Exitel Plus Tablets For Dogs.

Easimax Plus Tablets For Dogs. (UK),Exitel Plus (Denmark)

Exitel Tablets For Dogs (Germany, Norway, Spain).

Exitel vet.150 mg/144 mg/50 mg Tablets for dogs (Sweden)

Praziquantel, Febantel, Pyrantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Pork flavoured tablets.

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.

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 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.

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(S)

VPA 10987/078/001

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

Exitel Plus Tablets For Dogs.

Easimax Plus Tablets For Dogs. (UK),Exitel Plus (Denmark)

Exitel Tablets For Dogs (Germany, Norway, Spain).

Exitel vet.150 mg/144 mg/50 mg Tablets for dogs (Sweden)

Praziquantel, Febantel, Pyrantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Exitel Plus Tablets for dogs

Easimax Plus Tablets For Dogs. (UK),

Exitel Plus (Denmark)

Exitel Tablets For Dogs (Germany, Norway, Spain).

Exitel vet.150 mg/144 mg/50 mg Tablets for dogs (Sweden)

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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exitel Plus Tablets For Dogs.
Easimax Plus Tablets For Dogs. (UK),
Exitel Plus (Denmark)
Exitel Tablets For Dogs (Germany, Norway, Spain).
Exitel vet.150 mg/144 mg/50 mg Tablets for dogs (Sweden)
Praziquantel, Febantel, Pyrantel.

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

Prazitel Plus tablets are pale yellow pork-flavoured tablets with a cross breakline on one side . Each tablet contains Praziquantel 50 mg, 50 mg Pyrantel(equivalent to 144 mg Pyrantel Embonate) and Febantel 150 mg. The tablets can be divided into equal 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

In very rare cases, gastrointestinal disorders (diarrhoea, emesis) have been observed.

If you notice any serious effects or other effects not mentioned in this leaflet, 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 Exitel Plus 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.

For animal treatment only.

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.

Medicines should not be disposed of via wastewater or household waste.

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

12th February 2014

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.

VPA 10987/078/001