Exitel Plus Tablets for dogs

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.

NAME OF THE VETERINARY MEDICINAL PRODUCT
Exitel Plus Tablets For Dogs.
Praziquantel, Febantel, Pyrantel.

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.

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).

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.

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.

TARGET SPECIES
Dogs

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Single dose: For oral administration only.
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 tablets can be divided into equal halves or quarters.

Dosage table:	
Bodyweight (kg)	Tablets
½ – 2.5	¼
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	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.

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

WITHDRAWAL PERIOD
N/A

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.

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.

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
February 2014

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.

CAM Companion Animal Medicine

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