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

Strantel Plus XL Tablets for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Tablet.

4. 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.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For OTC products :

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral Use.

For OTC products:

1 tablet per 35 kg bodyweight.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only.

Only for those countries where the medicinal product is subject to medical prescription:

To be supplied only on veterinary prescription.

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 08749/3007

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

Strantel Plus XL Tablets for Dogs

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

Strantel Plus XL Tablets for Dogs

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

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strantel Plus XL Tablets for Dogs

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

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.

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

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.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 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 approx 17.5kg 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**
Approx 17.5kg	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

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
Shelf-life of half tablets: 14 days.

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 temperature storage conditions.Do not use after expiry date stated on the label.
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 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 can lead to toxicity.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

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.

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.”

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.

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

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

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: 13 June 2019