

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 blister of 2 tablets
Box containing 2 blisters of 2 tablets
Box containing 1 blister of 8 tablets
Box containing 13 blisters of 8 tablets
Box containing 52 blisters of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Tel flavoured tablets for medium and small dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
150 mg febantel / 50 mg pyrantel (as embonate) / 50 mg praziquantel

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2 tablets (1 blister)
4 tablets (2 blisters)
8 tablets (1 blister)
104 tablets (13 blisters)
104 tablets (52 blisters)

5. TARGET SPECIES

Dogs (adults and puppies).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Return any halved tablet to the opened blister and use within 7 days.

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

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4057

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 2 tablets
Blister of 8 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Tel flavoured tablets for medium and small dogs
150 mg febantel / 50 mg pyrantel / 50 mg praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER



3. EXPIRY DATE

{mm/yyyy}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 blister of 2 tablets
Box containing 2 blisters of 2 tablets
Box containing 2 blisters of 4 tablets
Box containing 12 blisters of 4 tablets
Box containing 24 blisters of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Tel flavoured tablets for large dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
525 mg febantel / 175 mg pyrantel (as embonate) / 175 mg praziquantel

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2 tablets (1 blister)
4 tablets (2 blisters)
8 tablets (2 blisters)
48 tablets (12 blisters)
48 tablets (24 blisters)

5. TARGET SPECIES

Dogs over 17.5 kg.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Return any halved tablet to the opened blister and use within 7 days.

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

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4057

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 2 tablets
Blister of 4 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Tel flavoured tablets for large dogs

525 mg febantel / 175 mg pyrantel / 175 mg praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER



3. EXPIRY DATE

{mm/yyyy}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Pro-Tel flavoured tablets for medium and small dogs
Pro-Tel flavoured tablets for large dogs

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

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer for the batch release:

Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Tel flavoured tablets for medium and small dogs
Pro-Tel flavoured tablets for large dogs

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

Each tablet contains:

Pro-Tel flavoured tablets for medium and small dogs
150 mg febantel / 50 mg pyrantel (as embonate) / 50 mg praziquantel

Pro-Tel flavoured tablets for large dogs
525 mg febantel / 175 mg pyrantel (as embonate) / 175 mg praziquantel

Excipients include liver flavouring.

Yellow brown, oval, divisible tablets.

4. INDICATIONS

Treatment of mixed infections by adult cestodes and nematodes 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* spp., *Taenia* spp., *Dipylidium caninum* (adult and immature forms).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Gastro-intestinal signs (vomiting, diarrhoea), possibly associated with lethargy, have been observed very rarely in spontaneous reports.

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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pro-Tel flavoured tablets for medium and small dogs
Dogs (adults and puppies).

Pro-Tel flavoured tablets for large dogs
Dogs (over 17.5 kg).

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral use.

- 1 tablet per 10 kg bodyweight, in one administration (for medium and small dogs).
- 1 tablet per 35 kg bodyweight, in one administration (for large dogs).

This is equivalent to 15mg/kg bodyweight febantel, 5mg/kg pyrantel (as embonate) and 5 mg/kg praziquantel.

Dosages are as follows:

Bodyweight (kg)	Number of tablets	
	Pro-Tel flavoured tablets for medium and small dogs [UK] Prowormer flavoured tablets for medium and small dogs [IE]	Pro-Tel flavoured tablets for large dogs [UK] Prowormer flavoured tablets for large dogs [IE] For dogs and large breed puppies over 17.5 kg.
3-5	½	
>5-10	1	
>10-15	1 ½	
>15-20	2	
17.5		½
>17.5 – 35		1
>35 – 52.5		1 ½
>52.5 – 70		2

The smaller tablet size should be used to achieve accurate dosing in dogs weighing less than 17.5 kg.

The tablets can be given to the dog with or without food. No starvation is needed before or after treatment.

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

The dosing program should be established by the veterinary surgeon.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 months intervals. It is advisable to treat the bitch at the same time as the puppies.

For the control of *Toxocara canis*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

For routine worm control adult dogs should be treated every 3 months.

In case of confirmed single infestation by cestode or by nematode, a monovalent product containing a cestocide or a nematocide alone should be used.

For routine treatment a single dose is recommended.

In the event of heavy roundworm infestation a repeat dose should be given after 14 days.

If an infestation caused by *Echinococcus (E.granulosus)* is detected in dogs, a repetition of the treatment is recommended for safety purpose.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Return any halved tablet to the opened blister and use within 7 days.
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 blister after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species

As precautionary measure to prevent the establishment of *Echinococcus multilocularis*, it is recommended that all dogs entering the country be treated with praziquantel.

Dogs kept together or in kennels should be treated at the same time.

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

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts such as fleas, mice etc is undertaken.

Special precautions for use in animals

The product is not recommended for use in puppies of less than 3 kg bodyweight.

User warnings

Wash hands after administration to the animal.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

Other precautions

Since it contains praziquantel, the product is effective against *Echinococcus* spp. which do not occur in all EU member states but are becoming more common in some. 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.

Use during pregnancy or lactation

Do not use in pregnant bitches during the first 4 weeks of pregnancy.

The product may be used during lactation (see Section 4.9 below).

Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine, as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Plasma concentrations of praziquantel may be decreased by concomitant administration with drugs that increase the activity of cytochrome P-450 enzymes (e.g. dexamethasone, phenobarbital).

Concurrent use with other cholinergic compounds can lead to toxicity.

Overdose

In safety studies, single doses of 5 times (4 times in very young puppies) 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 products should be disposed of in accordance with local requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

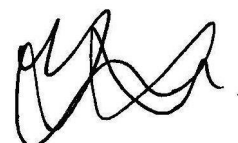
15. OTHER INFORMATION

The tablets are flavoured and consequently taken by most dogs voluntarily.

Pack sizes:

Pro-Tel flavoured tablets for medium and small dogs [UK] Prowormer flavoured tablets for medium and small dogs [IE]	Pro-Tel flavoured tablets for large dogs [UK] Prowormer flavoured tablets for large dogs [IE]
Box containing 1 blister of 2 tablets Box containing 2 blisters of 2 tablets Box containing 1 blister of 8 tablets Box containing 13 blisters of 8 tablets Box containing 52 blisters of 2 tablets	Box containing 1 blister of 2 tablets Box containing 2 blisters of 2 tablets Box containing 2 blisters of 4 tablets Box containing 12 blisters of 4 tablets Box containing 24 blisters of 2 tablets

Not all pack sizes may be marketed.



Approved: 12 October 2022