PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 2 to 48 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cestem flavoured tablets for large dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs over 17.5 kg.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 7 days
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

Return any halved tablet to the open blister.

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

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5053

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cestem

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

525 mg febantel / 175 mg pyrantel (as embonate) / 175 mg praziquantel

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cestem flavoured tablets for large dogs

2. Composition

Each tablet contains:
525 mg febantel / 175 mg pyrantel (as embonate) / 175 mg praziquantel
Yellow brown, oval, divisible tablet, with liver flavouring.

3. Target species

Dogs (weighing at least 17.5 kg)

4. Indications for use

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

6. Special warnings

Special precautions for safe use in the target species:
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 infection may reoccur unless control of intermediate hosts such as fleas, mice etc is undertaken.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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 (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Pregnancy and lactation:

Do not use in pregnant bitches during the first 4 weeks of pregnancy. The product may be used during lactation.

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.

7. Adverse events

Dogs*:*

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, Diarrhoea Lethargy[1]

[1] associated with vomiting and/or diarrhoea

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use. For dogs and large breed puppies over 17.5 kg.

15 mg febantel/kg bodyweight , 5 mg pyrantel (as embonate)/kg bodyweight and 5 mg praziquantel/kg bodyweight. This is equivalent to 1 tablet per 35 kg bodyweight, in one administration.

Dosages are as follows:

Body weight (kg)	Tablet quantity
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 correct dosage, body weight should be determined as accurately as possible.

The dosing program should be established by the veterinary surgeon.

As a general rule, 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 month 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 preferred.

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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Return any halved tablet to the opened blister.
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 carton and blister after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 7 days.

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.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5053

Pack sizes:
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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel. 01628 334056
email technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

Or
Ceva Santé Animale, Boulevard de la communication, Zone autoroutière, 53950 Louverné France

17. Other information

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

Pharmacodynamic properties

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 gastro- intestinal (GI) 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.

Pharmacokinetic particulars

After oral administration to dogs, praziquantel is extensively and quickly absorbed from the gastro-intestinal tract. Maximum plasma concentration of 752 µg/L is obtained in less than 2 hours. It is rapidly and extensively metabolised in the liver into hydroxylated derivatives of the parent compound, then rapidly eliminated, mainly in urine.

After oral administration to dogs, febantel is moderately absorbed from the gastro-intestinal tract. Febantel is rapidly metabolised in the liver into fenbendazole and its hydroxy and oxidative derivatives like oxfendazole. Maximum plasma concentration of fenbendazole (173 µg/L) is obtained after about 5 hours. Maximum plasma concentration of oxfendazole (147 µg/L) is obtained after about 7 hours. The excretion occurs mainly in the faeces.

After oral administration to dogs, pyrantel embonate is poorly absorbed. Maximum plasma concentration of 79 µg/L is obtained after about 2 hours. It is rapidly and extensively metabolised in the liver, then rapidly excreted, mainly in the faeces (the unchanged form) and in urine (the metabolites).

NFA-VPS

To be supplied only on veterinary prescription.

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 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

Cestem flavoured tablets for large dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One 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
Once opened, 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 Sante Animale
8 rue de Logrono
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 14966/5053

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

Cestem flavoured tablets for large dogs.
525 mg febantel / 175 mg pyrantel (as embonate) / 175 mg praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

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:
Cestem 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 Sante Animale
8 rue de Logrono
33500 Libourne
France

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

Or
Ceva Santé Animale, Boulevard de la communication, Zone autoroutière, 53950 Louverné France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cestem flavoured tablets for large dogs
Febantel / Pyrantel (as embonate) / Praziquantel

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

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

Yellow brown, oval, divisible tablet, with liver flavouring.

4. INDICATION(S)

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 cases of hypersensitivity to the active substances 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

Dogs (over 17.5 kg).

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

Oral use. For dogs and large breed puppies over 17.5 kg.

15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (as embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 35 kg bodyweight, in one administration.

Dosages are as follows:

Body weight (kg)	Tablet quantity
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.
As a general rule, 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 month 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 preferred.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species
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
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.

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.

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 (symptoms, emergency procedures, antidotes)
In safety studies, single doses of 5 times (4 times in very young puppies) the recommended dose or greater gave rise to occasional vomiting.

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.

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

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

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

Pharmacodynamic properties

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 gastro- intestinal (GI) 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.

Pharmacokinetic particulars

After oral administration to dogs, praziquantel is extensively and quickly absorbed from the gastro-intestinal tract. Maximum plasma concentration of 752 µg/L is obtained in less than 2 hours. It is rapidly and extensively metabolised in the liver into hydroxylated derivatives of the parent compound, then rapidly eliminated, mainly in urine.

After oral administration to dogs, febantel is moderately absorbed from the gastro-intestinal tract. Febantel is rapidly metabolised in the liver into fenbendazole and its hydroxy and oxidative derivatives like oxfendazole. Maximum plasma concentration of fenbendazole (173 µg/L) is obtained after about 5 hours. Maximum plasma concentration of oxfendazole (147 µg/L) is obtained after about 7 hours. The excretion occurs mainly in the faeces.

After oral administration to dogs, pyrantel embonate is poorly absorbed. Maximum plasma concentration of 79 µg/L is obtained after about 2 hours. It is rapidly and extensively metabolised in the liver, then rapidly excreted, mainly in the faeces (the unchanged form) and in urine (the metabolites).

Pack sizes:

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.

Gavin Hall
Approved: 21 October 2025