

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

X-Spectra flavoured tablets for large dogs [UK]
Cestem F XL tablets for dogs [FR]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
525 mg febantel / 175 mg pyrantel / 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.

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

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
To be supplied only on veterinary prescription. [FR]

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
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4058

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

X-Spectra flavoured tablets for large dogs [UK]
Cestem F XL tablets for dogs [FR]
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

X-Spectra flavoured tablets for medium and small dogs [UK]
X-Spectra flavoured tablets for large dogs [UK]
Cestem F tablets for dogs [FR]
Cestem F XL tablets for dogs [FR]

**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
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer for the batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

X-Spectra flavoured tablets for medium and small dogs [UK]
Cestem F tablets for dogs [FR]

X-Spectra flavoured tablets for large dogs [UK]
Cestem F XL tablets for dogs [FR]

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

Each tablet contains:

X-Spectra flavoured tablets for medium and small dogs [UK]
Cestem F tablets for dogs [FR]
150 mg febantel / 50 mg pyrantel / 50 mg praziquantel

X-Spectra flavoured tablets for large dogs [UK]
Cestem F XL tablets for dogs [FR]
525 mg febantel 175 mg / pyrantel 175 mg / praziquantel

Excipients include liver flavouring.

Yellow brown, oval, divisible tablets.

4. INDICATIONS

Treatment of mixed infections by 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* species, (*E. Granulosus*, *E. Multilocularis*), *Taenia* species (*T. hydatigena*, *T. pisiformis*, *T. taeniformis*), *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

X-Spectra flavoured tablets for medium and small dogs [UK]

Cestem F tablets for dogs [FR]

Dogs.

X-Spectra flavoured tablets for large dogs [UK]

Cestem F XL tablets for dogs [FR]

Dogs.

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

Oral use.

- 1 tablet per 10 kg bodyweight, in a single administration (for medium and small dogs).

- 1 tablet per 35 kg bodyweight, in a single administration (for large dogs).

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

Dosages are as follows:

Bodyweight (kg)	Number of tablets	
	X-Spectra flavoured tablets for medium and small dogs [UK] Cestem F tablets for dogs [FR]	X-Spectra flavoured tablets for large dogs [UK] Cestem F XL tablets for dogs [FR] 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.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNING(S)

Special warnings for each target species

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. To minimise the risk of reinfestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

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.

Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine or Levamisole. , as the anthelmintic effects of pyrantel 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 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020

15. OTHER INFORMATION

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

Pack sizes:

X-Spectra flavoured tablets for medium and small dogs [UK] Cestem F tablets for dogs [FR]	X-Spectra flavoured tablets for large dogs [UK] Cestem F XL tablets for dogs [FR]
Box containing 1 blister of 2 tablets	Box containing 1 blister of 2 tablets
Box containing 2 blisters of 2 tablets	Box containing 2 blisters of 2 tablets
Box containing 1 blister of 8 tablets	Box containing 2 blisters of 4 tablets
Box containing 13 blisters of 8 tablets	Box containing 12 blisters of 4 tablets
Box containing 52 blisters of 2 tablets	Box containing 24 blisters of 2 tablets

Not all pack sizes may be marketed.



Approved 24 June 2020