# 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

X-Spectra 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.

## 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 REACH AND SIGHT 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 15052/4055

## 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

X-Spectra 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.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET FOR

X-Spectra flavoured tablets for medium and small dogs
X-Spectra 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

Or

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

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

X-Spectra flavoured tablets for medium and small dogs

X-Spectra flavoured tablets for large dogs

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

Each tablet contains:

X-Spectra flavoured tablets for medium and small dogs
150 mg febantel / 50 mg pyrantel / 50 mg praziquantel

X-Spectra flavoured tablets for large dogs
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
Dogs.

X-Spectra flavoured tablets for large dogs
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:

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

**Pack sizes:**

| X-Spectra flavoured tablets for medium and small dogs | X-Spectra flavoured tablets for large dogs |
|---|---|
| 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.

*Gavin Hall*
Approved: 22 June 2024