PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIPYRAN XL 175 mg / 175 mg / 525 mg TABLETS FOR DOGS

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active ingredients:
Praziquantel .....175 mg
Pyrantel .....175 mg
(equivalent to 504.43 mg of pyrantel embonate)
Febantel .....525 mg

3. PACK SIZES

1 x 2 tablets
2 x 2 tablets
5 x 2 tablets
12 x 2 tablets
16 x 2 tablets
24 x 2 tablets
30 x 2 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}

Any divided tablet portion should be immediately discarded and not stored.

9. SPECIAL STORAGE PRECAUTIONS

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

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 20634/4008

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister of PVC and aluminium}

1. NAME OF THE VETERINARY MECIDINAL PRODUCT

ZIPYRAN XL

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains:

Praziquantel …….. 175 mg
Pyrantel ……. 175 mg
(equivalent to 504.43 mg of pyrantel embonate)
Febantel …… 525 mg

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

ZIPYRAN XL 175 mg / 175 mg / 525 mg tablets for dogs

2. Composition

Each tablet contains:

Active ingredients:
Praziquantel ……..175 mg
Pyrantel.....175 mg
(equivalent to 504.43 mg of pyrantel embonate)
Febantel ……525 mg

Yellowish oblong scored tablet, divisible into two equal parts.
Beef flavoured tablets.

3. Target species

Dogs.

4. Indications for use

Treatment of mixed infections by adult cestodes and nematodes of the following species:

Nematodes:
Hookworms: *Ancylostoma caninum*
Uncinaria Stenocephala
Ascarids*:* *Toxocara canis*
Toxascaris leonina

Cestodes:
Tapeworms*:* *Taenia spp*
Dipylidium caninum

5. Controindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
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 and source of infection for one common type of tapeworm – *Dipylidium caninum*.
Tapeworm infestation may reoccur unless control of intermediate hosts as well as the environment is undertaken concurrently to the treatment.

Special precautions for safe use in the target species:
In debilitated or heavily infested animals, the veterinary medicinal product should be used only after evaluation of the risk / benefit by the veterinarian.
Digestive haemorrhages (diarrhoea, bloody stools and even deaths) provoked by worm lysis may result from anthelminthic treatment in cases of heavy infestations.
In dogs less than 6 weeks old, tapeworm infections are highly uncommon. Treatment of animals less than 6 weeks old with a fixed combination veterinary medicinal product against cestodes and nematodes may, therefore, not be necessary.
The active substances are not known to cause particular adverse effects in young animals. Nevertheless the safety of the formulation has not been established in dogs less than 5 months of age.
Roundworm and hookworm infections: In some animals, *Ancylostoma caninum* and *Toxocara canis* may not be eradicated by the treatment, resulting in a continued risk of egg shedding into the environment. Follow-up examinations of the faeces are advisable and according to the results of these examinations, treatment with a nematocidal veterinary medicinal product may be carried out, if necessary.
To minimise the risk of re-infestation and new infestation, excreta should be collected and properly disposed out of for 24 hours following treatment

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
In case of accidental contact wash hands thoroughly
People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product
Wash hands after use.

Pregnancy and lactation:
Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.
The safety of the veterinary medicinal product has not been investigated during the 1st and 2nd third of pregnancy.
Do not use in pregnant bitches during the first four weeks of gestation
The veterinary medicinal 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:
Doses higher than 3 times the recommended dose can cause digestive disorders (vomiting and diarrhea).

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hyperactivity Anorexia Lethargy Gastrointestinal disturbances (diarrhoea and vomiting)

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.

Dosage: the recommended dose is 5 mg of Praziquantel, 5 mg of Pyrantel (embonate) and 15 mg of Febantel per kg of body weight (equivalent to one tablet/35 kg bw) in accordance with the following table:

Animal Body weight (kg)	Nº of tablets
17.5	½
> 17.5 - 35	1
> 35 – 52.5	1 ½
> 52.5 – 70	2

To ensure a correct dosage, body weight should be determined as accurately as possible.
For single oral treatment only.
The tablets are administered by placing whole and/or divided tablets at the back of the tongue for forced swallowing.

9. Advice on correct administration

The tablets are administered by placing whole and/or half tablets at the back of the tongue for forced swallowing.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
In cases of confirmed single infestation by cestodes or nematodes, a monovalent veterinary medicinal product containing a cestocide or a nematocide alone should be used.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions
Do not use this veterinary medicinal product after the expiry date stated on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life of the divided tablet after first opening the immediate packaging: any divided tablet portion should be immediately discarded and not stored

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 or pharmacist 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 size

Vm 20634/4008

Pack sizes:
Cardboard box with 1 blister of 2 tablets
Cardboard box with 2 blisters of 2 tablets
Cardboard box with 5 blisters of 2 tablets
Cardboard box with 12 blisters of 2 tablets
Cardboard box with 16 blisters of 2 tablets
Cardboard box with 24 blisters of 2 tablets
Cardboard box with 30 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 and manufacturer responsible for batch release and contact details to report suspected adverse events:
Laboratorios Calier, S.A.
C/ Barcelonès 26
Polígono Industrial El Ramassà
Les Franqueses del Vallès
Barcelona
08520 SPAIN
Tel: +34 93 8495133
E-mail: pharmacovigilance@calier.es

17. Other information

NFA-VPS

Approved 20 October 2025
Gavin Hall