PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIPYRAN TABLETS FOR DOGS
Praziquantel, Pyrantel embonate, Febantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Active ingredients:
Praziquantel .....50 mg
Pyrantel (as pyrantel embonate).....50 mg
Febantel .....150 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

Cardboard box containing 1 blister of 2 tablets
Cardboard box containing 2 blisters of 2 tablets
Cardboard box containing 1 blister of 4 tablets
Cardboard box containing 3 blisters of 2 tablets
Cardboard box containing 4 blisters of 2 tablets
Cardboard box containing 1 blister of 10 tablets.
Cardboard box containing 25 blisters of 10 tablets
Not all pack sizes may be marketed.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

Laboratorios Calier, SA
C/ Barcelonès 26 (Plà del Ramassar)
08520 Les Franqueses del Valles (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20634/4004

17. MANUFACTURER'S BATCH NUMBER

Batch

OTHER INFORMATION

Beef-flavoured tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIPYRAN TABLETS FOR DOGS
Praziquantel, Pyrantel embonate, Febantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

ZIPYRAN TABLETS FOR 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 and manufacturer responsible for batch release

Laboratorios Calier, SA
C/ Barcelonès 26 (Plà del Ramassar)
08520 Les Franqueses del Valles (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZIPYRAN TABLETS FOR DOGS
Praziquantel, Pyrantel embonate, Febantel

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

Each tablet contains:

Active ingredients:
Praziquantel .....50 mg
Pyrantel (as pyrantel embonate).....50 mg
Febantel .....150 mg

Yellowish round scored tablet, divisible into four equal parts.

4. INDICATION(S)

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. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Dogs

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

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
For single oral treatment only.
The recommended dose is 5 mg of Praziquantel, 5 mg of Pyrantel (as

embonate) and 15 mg of Febantel per kg of body weight (equivalent to one

tablet/10 kg bw) in accordance with the following table:

Animal Body weight (kg)	Nº of tablets
2.5 – 5	½
5 – 10	1
10 – 15	1 ½
15 – 20	2
20 - 25	2 ½
25 - 30	3

The tablets are administered by placing whole and/or divided tablets at the back of the tongue for forced swallowing.

To further improve accuracy of dosing, tablets may be quartered

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 product containing a cestocide or a nematocide alone should be used.

10. WITHDRAWAL PERIOD

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

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 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 use in animals

In debilitated or heavily infested animals, the 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 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 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

Use during pregnancy, lactation or lay
Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.
The safety of the product has not been investigated during pregnancy.
Do not use in pregnant bitches during the first four weeks of gestation

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), if necessary
Doses higher than 3 times the recommended dose can cause digestive disorders (vomiting and diarrhea).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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
15. OTHER INFORMATION

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Cardboard box containing 1 blister of 4 tablets
Cardboard box containing 3 blisters of 2 tablets
Cardboard box containing 4 blisters of 2 tablets
Cardboard box containing 1 blister of 10 tablets
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Beef-flavoured tablets

Approved 18 May 2017