ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FELIMINTIC, 80/20 mg, tablets for cats

Pyrantel/Praziquantel
Cats (> 1 kg)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substances
Pyrantel 80.0 mg
(equivalent to 230 mg of pyrantel embonate)
Praziquantel 20.0 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

Cardboard box of 2 tablets.

5. TARGET SPECIES

Cats.

6. INDICATION(S)

For the treatment of infestations by gastrointestinal parasites sensitive to praziquantel and pyrantel.
For the treatment of mixed infestations with the roundworm *Toxocara cati* (adult), hookworms *Ancylostoma tubaeforme* and *braziliense* (adults) and the tapeworm *Taenia taeniaeformis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special temperature storage conditions.
Do not keep the remaining portion of the divided tablets after opening.

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

Disposal: read the 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

Domes Pharma
3 rue André Citroën
63430 Pont-du Chateau
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 54982/4010

17. MANUFACTURER'S BATCH NUMBER

<Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{PVC/aluminium thermosealed blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FELIMINTIC, 80/20 mg, tablets for cats

Pyrantel 80.0 mg (as embonate salt)
Praziquantel 20.0 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

<Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
FELIMINTIC, 80/20 mg, tablets for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Domes Pharma
3 rue André Citroën
63430 Pont-du Chateau
France

Manufacturer responsible for batch release:
EUROPHARTECH
34 rue Henri Matisse
63370 LEMPDES
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FELIMINTIC, 80/20 mg, tablets for cats
Pyrantel embonate
Praziquantel

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

Each tablet contains:

Active substances
Pyrantel.....80.0 mg
(equivalent to. 230 mg of pyrantel embonate)
Praziquantel.....20.0 mg

Yellow tablet with 1 scored line. The tablet can be divided in half.

4. INDICATION(S)

Treatment of mixed infestations with the following roundworms and tapeworms:
• adult nematoda:
- *Toxocara cati*
- *Ancylostoma tubaeforme, Ancylostoma braziliense*

• cestoda:
- *Taenia taeniaeformis*

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to active substances or to any of the excipients.
Do not use simultaneously with cholinergic compounds (e.g. piperazine).
Do not use in kittens less than 8 weeks of age or weighing less than 1 kg bodyweight.

6. ADVERSE REACTIONS

Treated animals may present transient diarrhoea (very common) related to the elimination of parasites.
In very rare cases mild and other transient digestive tract disorders such as hypersalivation and/or vomiting may occur and mild and transient neurological disorders such as ataxia may occur in very rare cases.

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, including isolated reports).

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

7. TARGET SPECIES

Cats.

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

Oral use.
5 mg/kg praziquantel and 20 mg/kg pyrantel (57.5 mg as pyrantel embonate), corresponding to 1 tablet per 4 kg bodyweight, in a single administration.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible.

Dosages are shown in the table below:

Bodyweight (kg)	Number of tablets per intake
1.0 – 2.0 kg	$^1/_2$
2.1 – 4.0 kg	1
4.1 – 6.0 kg	1 + $^1/_2$
6.1 – 8.0 kg	2

The tablets should be given directly into the mouth or mixed with food. No dietary measures are necessary.

In *Toxocara cati* infestation, especially in kittens, complete elimination cannot be expected, and the risk of infection for humans can persist. Repeat treatments should be carried out with a suitable *Toxocara cati* product at 14 day intervals until 2-3 weeks after weaning.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions.
Shelf life after opening the immediate packaging: Unused half tablets must be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Taenia taeniaeformis infestation is certain to re-occur unless control of intermediate hosts such rodents is undertaken.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, this may be due to underestimation of body weight or misadministration of the product.

Unnecessary use of antiparasitics or use deviating from the instruction given in the SPC may increase selection pressure and lead to reduced activity.
The decision of use the product should be based on confirmation of the parasitic species and burden or the risk of infection based on its epidemiological features for each individual animal.
The possibility that other animals in the same household can be a source of re-infection with target parasites should be considered and these should be treated as necessary with an appropriate product. The use of the product should take into account local information about susceptibility of the target parasites where available.

Tapeworm infestation occurs in cats at the earliest in the third week of life.

Special precautions for use in animals:

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use of the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Discard any unused parts of tablets.

Use during pregnancy, lactation or lay:
Praziquantel and pyrantel do not show effects on reproductive parameters in cats.
No embryotoxic, foetotoxic or teratogenic effects have been found in laboratory animals (rat, mouse) for pyrantel and praziquantel and in cats for praziquantel.

The safety of the veterinary medicinal product has not been established in pregnant or lactating cats after oral administration.
The use is not recommended during pregnancy. Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with cholinergic compounds (e.g. piperazine), because the specific activities of cholinergic compounds (neuromuscular paralysis of the parasites) can inhibit the efficacy of pyrantel (spastic paralysis of the parasites).

Overdose (symptoms, emergency procedures, antidotes):
At three times the recommended dose of the fixed combination praziquantel/pyrantel, vomiting and diarrhoea have been observed.

Major incompatibilities:
None known.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Packages size:
Cardboard box containing one blister of 2 tablets.

Marketing authorization number:
Vm 54982/4010

Classification of the medicinal product in terms of dispensing.
For animal treatment only.
For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Approved 07 October 2022