PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimintic 80 mg / 20 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet of 320 mg contains:
Pyrantel (as pyrantel embonate)……. 80 mg
(equivalent to 230 mg of pyrantel embonate)
Praziquantel……..... 20 mg

3. PACKAGE SIZE

2 tablets

4. TARGET SPECIES

Cat

5. INDICATIONS

For the treatment of mixed infestations with the roundworm *Toxocara cati* (adult), hookworms *Ancylostoma tubaeforme* and *braziliense* (adults) and the tapeworm *Taenia taeniaeformis.*

6. ROUTES OF ADMINISTRATION

Oral use

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

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

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

DOMES PHARMA

14. MARKETING AUTHORISATION NUMBERS

Vm 54982/4010

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimintic

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pyrantel 80 mg / Praziquantel 20 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

Felimintic 80 mg / 20 mg tablets for cats

2. Composition

One tablet of 320 mg contains:
Pyrantel (as pyrantel embonate) ……. 80 mg
(equivalent to 230 mg of pyrantel embonate)
Praziquantel……..…….. 20 mg
Yellow, round tablet with 1 scored line on each face. The tablet can be divided in half.

3. Target species

Cat.

4. Indications for use

For the treatment of mixed infestations caused by:
• adult nematoda:
- *Toxocara cati*
- *Ancylostoma tubaeforme*
- *Ancylostoma braziliense*

• cestoda:
- *Taenia taeniaeformis*

5. Contraindications

Do not use in cases of hypersensitivity to the 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.
Please see section 6.

6. Special warnings

Special warnings:
Taenia taeniaeformis infestation is certain to re-occur unless control of intermediate hosts such as 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 leaflet 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 safe use in the target species:
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.

Pregnancy:
The use is not recommended during pregnancy.
Laboratory studies in rats and mouses for pyrantel and praziquantel have not produced any evidence of teratogenic, foetotoxic and embryotoxic effects.
Laboratory studies in cats for praziquantel have not produced any evidence of teratogenic, foetotoxic and embryotoxic effects.

Lactation:
Can be used during lactation.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Fertility:
Praziquantel and pyrantel do not show effects on reproductive parameters in cats.

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:
At three times the recommended dose of the fixed combination praziquantel/pyrantel, vomiting and diarrhoea have been observed.

Major incompatibilities:
None known.

7. Adverse events

Cats:
Very common (> 1 animal / 10 animals treated) :
Diarrhoea[1, 2]

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Digestive tract disorder (e.g. hypersalivation, vomiting)[3]
Neurological disorder (e.g.ataxia (incoordination))[3]
[1] related to the elimination of parasites
[2] transient
[3] mild and transient

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 https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes 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 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 days intervals until 2-3 weeks after weaning.

9. Advice on correct administration

Not applicable.

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 which is stated on the blister after Exp. The expiry date refers to the last day of that month.
Shelf life after opening the immediate packaging: Unused half tablets must be discarded.

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 not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation numbers:
Vm 54982/4010

Pack sizes:
Cardboard box of 1 blister of 2 tablets.

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 contact details to report suspected adverse reactions:
DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

Manufacturer responsible for batch release:
EUROPHARTECH
34 rue Henri Matisse
63370 Lempdes
France

17. Other information

NFA-VPS

Gavin Hall

Approved: 17 January 2025