Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

FELIMINTIC, 80/20 mg tablets for cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of infestations by gastrointestinal parasites sensitive to praziquantel and pyrantel.
For the treatment of mixed infestations caused by:

- adult nematoda:
  - *Toxocara cati*
  - *Ancylostoma tubaeforme*
  - *Ancylostoma braziliense*

- cestoda:
  - *Taenia taeniaeformis*

4.3 Contraindications

Do not use in known cases of hypersensitivity to pyrantel, praziquantel 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 4.7 and section 4.8.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
None.

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 by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions
None.

4.6 Adverse reactions (frequency and seriousness)

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 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 investigated in pregnant or lactating cats.
The use is not recommended during pregnancy. Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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).

4.9 Amounts to be administered and administration route

For 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics
ATCvet code: QP52AA51

5.1 Pharmacodynamic properties

The product is an anthelmintic containing praziquantel, a pyrazinoisoquinoline derivative, and pyrantel, a tetrahydropyrimidine derivative (as the embonate salt), active against nematodes and cestodes.

Praziquantel acts on cestodes; the spectrum of action includes *Taenia taeniaeformis*. It acts against all stages of development of these parasites in the cat intestine. Praziquantel is absorbed very rapidly through the parasite's surface and is distributed evenly inside the parasite. Both *in vitro* and *in vivo* severe damage to the parasite integument sets in very quickly, resulting in contraction and paralysis of the parasite. The basis for the rapid onset of action is above all the praziquantel-induced change in the permeability of the parasite membrane to Ca++, which leads to a dysregulation of the parasite metabolism.
No resistance to praziquantel has been reported in cats. The mechanism of resistance has been studied in mouse. In parasites less sensitive to praziquantel, a lower inhibition of hepatic drug-metabolising enzymes and a higher metabolism of praziquantel, leading to a lower exposure of the parasite has been found.
Pyrantel acts specifically on nematodes, in particular *Toxocara cati, Ancylostoma tubaeforme and Ancylostoma braziliense*. It acts as a cholinergic agonist similarly to nicotine, and causes spastic paralysis of the nematodes by a depolarising neuromuscular blockade. No resistance to pyrantel has been reported in cats. The mechanisms of resistance are not clearly identified, but appear to involve different subtypes of cholinergic receptors which bind to pyrantel in the parasite.

5.2 Pharmacokinetic particulars

Praziquantel is very rapidly and almost completely absorbed in the stomach and small intestine following oral administration. Maximum serum levels are already reached within 0.3 to 2 hours. Praziquantel is very rapidly distributed into all organs. The elimination half-lives of ^{14}C-praziquantel and its metabolites are between 2 and 3 hours. Praziquantel is rapidly metabolised in the liver. Among all metabolites, the main metabolite is the 4-hydroxycyclohexyl derivative of praziquantel. Praziquantel is completely eliminated within 48 hours in the form of its metabolites - between 40 and 71 % in the urine and, via the bile, between 13 and 30 % in the faeces.
The embonate salt of pyrantel is poorly absorbed from the gastrointestinal tract.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Pregelatinized starch
Pig liver flavour
Dried yeast
Magnesium stearate
Povidone K30

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

PVC/aluminium thermosealed blister containing two tablets.
Cardboard box containing one blister.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Domes Pharma SC
57 rue des Bardines
LEMPDES 63370
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10386/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 September 2017

10 DATE OF REVISION OF THE TEXT

March 2021