[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimintic 80 mg / 20 mg tablets for cats [AT, BE, DE, ES, IE, IT, LU, NL, PT, UK(NI)]
Multivermyx Biocanina 80 mg / 20 mg tablets for cats [FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet of 320 mg contains:

Active substances:
Pyrantel……. 80 mg
(as pyrantel embonate)
(equivalent to 230 mg of pyrantel embonate)
Praziquantel…….. 20 mg

Excipients:

Qualitative composition of excipients and other constituents
Microcrystalline cellulose
Pregelatinized starch
Pig liver flavour
Dried yeast
Magnesium stearate
Povidone K30

Yellow, round tablet with 1 scored line on each face. The tablet can be divided in half.

3. CLINICAL INFORMATION

3.1 Target species

Cat.

3.2 Indications for use for each target species

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

• cestoda:
- *Taenia taeniaeformis*

3.3 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 3.7 and section 3.8.

3.4 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 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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)[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details..

3.7 Use during pregnancy, lactation or lay

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

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.

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

3.8 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).

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

< Not applicable. >

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after opening the immediate packaging: Unused half tablets must be discarded.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box of 1 PVC/aluminium thermosealed blister of 2 tablets.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

7. MARKETING AUTHORISATION NUMBER(S)

AT: 837794
BE: BE-V516346
DE: 402419.00.00
ES: 3573 ESP
FR: FR/V/0883707 5/2015
IE: VPA23340/004/001
IT: AIC n° 105107015 (1 blister of 2 tablets)
LU: V 355/17/12/1646
NL: REG NL 120664
PT: 1114/01/17RFVPT
UK(NI): XXXX

8. DATE OF FIRST AUTHORISATION

AT: 03/08/2017
BE: 20/08/2017
DE: 14/07/2017
ES: 21/07/2017
FR: 03/07/2015
IE: 15/09/2017
IT: 03/06/2021
LU: 03/07/2015
NL: 20/09/2017
PT: 27/06/2017
UK(NI): 28/06/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

XX/XXXX

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. [AT, DE, ES, FR, PT]
Veterinary medicinal product not subject to prescription. [BE, IE, IT, LU, NL, UK(NI)]

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary)

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 mg / 20 mg tablets [AT, BE, DE, ES, IE, IT, LU, NL, PT, UK(NI)]
Multivermyx Biocanina 80 mg / 20 mg tablets [FR]

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

AT: 837794
BE: BE-V516346
DE: 402419.00.00
ES: 3573 ESP
FR: FR/V/0883707 5/2015
IE: VPA23340/004/001
IT: AIC n° 105107015 (1 blister of 2 tablets)
LU: V 355/17/12/1646
NL: REG NL 120664
PT: 1114/01/17RFVPT
UK(NI): XXXX

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimintic [AT, BE, DE, ES, IE, IT, LU, NL, PT, UK(NI)]
Multivermyx Biocanina [FR]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pyrantel 80 mg / Praziquantel 20 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Felimintic 80 mg / 20 mg tablets for cats [AT, BE, DE, ES, IE, IT, LU, NL, PT, UK(NI)]
Multivermyx Biocanina 80 mg / 20 mg tablets for cats [FR]

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 either the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system : <{national system details}.>

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 or household waste.
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. [AT, DE, ES, FR, PT]

Veterinary medicinal product not subject to prescription. [BE, IE, IT, LU, NL, UK(NI)]

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:
AT: 837794
BE: BE-V516346
DE: 402419.00.00
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IT: AIC n° 105107015 (1 blister of 2 tablets)
LU: V 355/17/12/1646
NL: REG NL 120664
PT: 1114/01/17RFVPT
UK(NI): XXXX

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

15. Date on which the package leaflet was last revised

XX/XXXX
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary)

16. Contact details

Marketing authorisation holder:
DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

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

<Local representatives and contact details to report suspected adverse reactions:>
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

[For MRP/DCP/SRP and national procedures: To be completed nationally.]”