

## PROPOSAL FOR SPC

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MULTIVERMYX Chat, 80/20 mg, tablet [FR]

FELIMINTIC, 80/20 mg, tablets for cats [AT, BE, DE, IE, IT, LU, NL, PT, ES, UK]

### 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

Treatment of mixed infestations with the following roundworms and tapeworms:

- adult nematoda:

- *Toxocara cati*

- *Ancylostoma tubaeforme*, *Ancylostoma braziliense*

- 

- cestoda:

- *Taenia taeniaeformis*

#### 4.3 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.

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.

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.

#### **4.5 Special precautions for use**

##### 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.

#### **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 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).

#### **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 established in pregnant or lactating cats after oral administration.

The use is not recommended during pregnancy. Can be used during lactation.

#### **4.8 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).

#### **4.9 Amounts to be administered and administration route**

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	$\frac{1}{2}$
2.1 – 4.0 kg	1
4.1 – 6.0 kg	$1 + \frac{1}{2}$
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 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<sup>++</sup>, 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 <sup>14</sup>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.

Shelf life after opening the immediate packaging: Unused half tablets must be discarded.

### **6.4. Special precautions for storage**

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

### **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 product 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

63370 LEMPDES

FRANCE

## **8. MARKETING AUTHORISATION NUMBER(S)**

FR/X/XXXXXXXX X/XXXX

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

03/07/2015

**10 DATE OF REVISION OF THE TEXT**

XX/XX/2017

**OUTER PACKAGING: CARDBOARD BOX**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

cardboard box

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

MULTIVERMYX Chat, 80/20 mg, tablet [FR]

FELIMINTIC, 80/20 mg, tablets for cats [AT, BE, DE, IE, IT, LU, NL, PT, ES, UK]

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 SC  
57 rue des Bardines  
63370 LEMPDES  
FRANCE

**16. MARKETING AUTHORISATION NUMBER(S)**

FR/X/XXXXXXXX X/XXXX

**17. MANUFACTURER'S BATCH NUMBER**

<Lot> {number}

**IMMEDIATE PACKAGING: GLASS AMPOULS**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{PVC/aluminium thermosealed blister}

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FELIMINTIC, 80/20 mg, tablets for cats [AT, BE, DE, IE, IT, LU, NL, PT, ES, UK]

Pyrantel 80.0 mg (as embonate salt)

Praziquantel 20.0 mg

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

DOMES PHARMA SC

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

<Lot> {number}

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.



## PACKAGE LEAFLET

### PACKAGE LEAFLET FOR:

MULTIVERMYX Chat, 80/20 mg, tablet [FR]  
FELIMINTIC, 80/20 mg, tablets for cats [AT, BE, DE, IE, IT, LU, NL, PT, ES, UK]

#### 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 SC  
57 rue des Bardines  
63370 LEMPDES  
FRANCE

Manufacturer responsible for batch release:

EUROPHARTECH  
34 rue Henri Matisse  
63370 LEMPDES  
FRANCE

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MULTIVERMYX Chat, 80/20 mg, tablet [FR]  
FELIMINTIC, 80/20 mg, tablets for cats [AT, BE, DE, IE, IT, LU, NL, PT, ES, UK]  
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	$\frac{1}{2}$
2.1 – 4.0 kg	1
4.1 – 6.0 kg	$1 + \frac{1}{2}$
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**

<{MM/YYYY}>

**15. OTHER INFORMATION**

Packages size:

Cardboard box containing one blister of 2 tablets.

Marketing authorization number:

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.