

## I.B.1. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cestacat Cat flavour tablets ad us. vet.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

#### Active substances

Praziquantel	20.0 mg
Pyrantel embonate	230.0 mg

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Tablet for oral administration.

### 4. CLINICAL PARTICULARS

#### 4.1. Target species

Cat.

#### 4.2. Indications for use

Cestacat Cat is recommended for the treatment and control of all common tapeworm and roundworm infestation of cats and kittens including:

- \* ascarids: *Toxocara cati*, *Toxascaris leonina*  
(adult and late immature forms)
- \* hookworms: *Ancylostoma tubaeforme*, *Uncinaria stenocephala*
- \* tapeworms: *Echinococcus multilocularis*, *Taenia spp.*, *Dipylidium caninum* (adults and immature forms)

#### 4.3. Contra-indications

Pyrantel containing drugs can only be administered with great care to cachexic animals. The product cannot be used in case of allergy to the active ingredients or any of the excipients.

#### 4.4. Special warnings for each target species

None.

#### 4.5. Special precautions for use

##### Special precautions for use in animals

No special precautions are required.

##### Special safety precautions to be taken by the person administering the product to the animals

The general labour safety precautions must be observed. If swallowed seek medical assistance and display the label or package insert. In case of allergy to praziquantel or pyrantel pamoate avoid the contact with the product. Keep the animals in a closed area for 24 hours after deworming and the faeces, worms, worm joints and eggs should be burnt. The area around the animals should be adequately and regularly cleaned and disinfected and in the interests of good hygiene wash hands after cleaning. After treatment keep the children away from the cats for a few days.

#### 4.6. Adverse reactions (frequency and seriousness)

Acute toxicity of the product is >2000 mg/kg b.w. During the target animal safety tests no clinical, hematological or biochemical adverse reactions were detected even when the product was administered at the fivefold dose level. No side effects were observed during clinical trials.

#### 4.7. Use during pregnancy, lactation or lay

The product can also be safely administered to pregnant bitches.

#### 4.8. Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds since the antagonistic actions of pyrantel and piperazine may counterbalance/antagonize each other.

Equally, do not administer together with organophosphorus insecticide and diethylcarbamazine. Because of the similar mechanism of action and toxicology it is also advised to avoid the co-administration with morantel and levamisol.

#### 4.9. Amount(s) to be administered and administration route

*Dosage:*

One tablet per 4 kg of body weight.

<2 kg ½ tablet

2-4 kg 1 tablet

4-8 kg 2 tablets

*Method of administration:*

For oral use. The tablets can be given directly to the mouth or disguised in food (a piece of meat, sausage, etc.). Treatment immediately prior to feeding is recommended. For general deworming 1 treatment is enough but in case of heavy worm infection administer the product for 3 consecutive days and the treatment should be repeated in 14 days. Because of the hazard of reinfection the treatment should be repeated every 3 month.

**4.10. Overdose (symptoms, emergency procedures, antidotes)**

Overdosage of the product in the clinical practice may rarely occur because of good tolerance by the target species to be used in. In the target animal safety tests, the product failed to induce any toxic effect even when administered at a dosage of three times the recommended. If suspected toxic reactions do occur due to extreme overdosage, appropriate symptomatic treatment should be performed if necessary.

**4.11. Withdrawal periods**

Non applicable.

**5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: quinolone derivatives.

ATCvet Code: QP52AA51

**5.1 Pharmacodynamic properties**

The product is a broad-spectrum anthelmintic containing praziquantel and pyrantel pamoate as active substances. It exhibits a high activity against all common tapeworms and roundworms of cats also including several immature forms. Of the active ingredients, praziquantel is the most effective cestocidal agent used in the human and veterinary medicine that has 100% activity against *Echinococcus multilocularis* as well. Pyrantel embonate is known to be highly effective for the common ascarids (*Toxocara cati*, *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme*, *Uncinaria stenocephala*) of cats at single oral doses of 20 mg base per kg of body weight, whereas it has no sufficient action on the ascarids (*Trichuris vulpis*) of dogs.

According to the target animal safety tests, Cestral Cat tablets possess a high margin of safety, no side effects were induced even in fivefold overdose levels.

**5.2 Pharmacokinetic particulars**

No data available.

**6. PHARMACEUTICALS PARTICULARS**

**6.1. List of excipients**

Lactose-monohydrate

Starch

Povidon

Talc

Magnesium stearate

Carboximethyl-starch-sodium

**6.2. Incompatibilities**

Not applicable.

**6.3. Shelf-life**

Shelf-life from date of manufacture in original packaging: 2 years.

**6.4. Special precautions for storage**

Store under 25°C. Protect from direct sunlight.

**6.5. Nature and contents of container**

Primary container: strip packs of polyethylene/aluminium foil.

Secondary container: carton box.

Contents: 5x2 tablets in each box.

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

Any unused product or waste material should be disposed of in accordance with national requirements. The product cannot be released into natural waters.

**7. MARKETING AUTHORISATION HOLDER**

Lavet Pharmaceuticals Ltd.,

1161 Budapest, Ottó u. 14., Hungary

**8. MARKETING AUTHORISATION NUMBER**

3275/1/12 NÉBIH ÁTI (5x2 tablets)

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

Date of first authorization: 16 February, 1998.

Date of last renewal: 18 December, 2012.

**10. DATE OF REVISION OF THE TEXT**

18 December 2012

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Only for veterinary use. Over-the-counter. To be sold only by authorized distributors.

## I.B.2. LABELLING

### PARTICULARS TO APPEAR ON THE OUTER LABEL

Box of 5x2 tablets

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

Cestal Cat Flavour tablets ad us. vet.  
Praziquantel  
Pyrantel embonate

#### 2. STATEMENT OF ACTIVE SUBSTANCES

##### Active substances

Praziquantel	20.0 mg
Pyrantel pamoate	230.0 mg

#### 3. PHARMACEUTICAL FORM

Tablet.

#### 4. PACKAGE SIZE

5x2 tablets per box.

#### 5. TARGET SPECIES

Cats.

#### 6. INDICATIONS

The product is recommended for the treatment and control of all common tapeworm and roundworm infestation of cats and kittens including:

- \* ascarids: *Toxocara cati*, *Toxascaris leonine* (adult and late immature forms)
- \* hookworms: *Ancylostoma tubaeforme*, *Uncinaria stenocephala*
- \* tapeworms: *Echinococcus multilocularis*, *Taenia spp.*, *Dipylidium caninum* (adults and immature forms)

#### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

#### 8. WITHDRAWAL PERIOD

Not applicable.

#### 9. SPECIAL WARNINGS

Read the package insert before use.

#### 10. EXPIRY DATE

Expiry date: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Store below 25°C. Store in a dry place, protect from direct sunlight.

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

Any unused product or waste material should be disposed of in accordance with national requirements. The product cannot be released into natural waters.

#### 13. THE WORDS „FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Over-the-counter. To be sold only by authorized distributors.

#### 14. THE WORDS „KEEP OUT OF REACH AND SIGHT OF CHILDREN”

Keep out of reach and sight of children.

#### 15. NAME AND ADDRESS OF THE MARKETING AND MANUFACTURING AUTHORISATION HOLDER

LAVET Pharmaceuticals Ltd.  
H-1161 Budapest, 14. Ottó u., Hungary

#### 16. REGISTRATION NUMBER

Cestal Cat Flavour – EN – 05/06/2013

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

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

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

Cestral Cat Flavour tablets ad.us.vet.  
Praziquantel  
Pyrantel embonate

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

LAVET Pharmaceuticals Ltd.

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Batch {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PACKAGE LEAFLET FOR:**  
Cestál Cat Flavour tablets ad.us.vet.

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

Marketing authorisation holder: Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary  
Responsible for batch release: Lavet Pharmaceuticals Ltd., Kistarcsa, 2143 Batthyány u. 6., Hungary

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

Cestál Cat Flavour tablets ad.us.vet.  
Praziquantel  
Pyrantel embonate

**3. STATEMENT of ACTIVE SUBSTANCES**

**Active substances**

Praziquantel	20.0 mg
Pyrantel embonate	230.0 mg

**4. INDICATIONS**

For treatment and control of all major worm infections in cats as follows:

- ascarids: *Toxocara cati*, *Toxascaris leonina* (adult and late immature forms)
- hookworms: *Ancylostoma tubaeforme*, *Uncinaria stenocephala*
- tapeworms: *Echinococcus multilocularis*, *Taenia spp.*, *Dipylidium caninum* (adults and immature forms)

**5. CONTRA-INDICATIONS**

Pyrantel containing drugs can only be administered to cachexic animals with great care. The product cannot be used in case of allergy to the active ingredients or any of the excipients.

**6. UNDESIRABLE EFFECTS**

Acute toxicity of the product is >2000 mg/kg b.w. During the target animal safety tests no clinical, hematological or biochemical adverse reactions were detected even when the product was administered at the fivefold dose level. No side effects were observed during clinical trials. If side effects are seen please report to your veterinarian immediately.

**7. TARGET SPECIES**

Cats.

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

One tablet per 4 kg of body weight (which corresponds to the following dose rates of the active substances: praziquantel 5 mg/kg and pyrantel base 20 mg/kg).

<2 kg	½ tablet
2-4 kg	1 tablet
4-8 kg	2 tablets

**9. ADVICE ON CORRECT ADMINISTRATION**

The tablets can be given directly to the mouth of the cat or disguised in food (a piece of meat, sausage, etc.). For general deworming 1 treatment is enough. For oral use. No prior starvation is necessary. Because of the hazard of reinfection the treatment should be repeated every 3 month.

**10. WITHDRAWAL PERIOD**

Non applicable.

**11. SPECIAL STORAGE CONDITIONS**

Keep out of reach of children.  
Store under 25°C. Protect from direct sunlight.

**12. SPECIAL PRECAUTIONS**

*Special safety precautions to be taken by the person administering the product to the animals*

The general labour safety precautions must be observed. If swallowed seek medical assistance and display the label or package insert. In case of allergy to praziquantel or pyrantel pamoate avoid the contact with the product. Keep the animals in a closed area for 24 hours after deworming and the faeces, worms, worm joints and eggs should be burnt. The area around the animals should be adequately and regularly cleaned and disinfected and in the interests of good hygiene wash hands after cleaning. After treatment keep the children away from the cats for a few days.

*Use during pregnancy, lactation or lay*

The product can also be safely administered to pregnant queens.

*Interaction with other medicaments and other forms of interaction*

Do not use simultaneously with piperazine compounds since the antagonistic actions of pyrantel and piperazine may counterbalance/antagonize each other.

Equally, do not administer together with organophosphorus insecticide and diethylcarbamasine. Because of the similar mechanism of action and toxicology it is also advised to avoid the co-administration with morantel and levamisol.

*Overdose (symptoms, emergency procedures, antidotes)*

Overdose of the product in the clinical practice may rarely occur because of good tolerance by the target species to be used in. In the target animal safety tests, the product failed to induce any toxic effect even when administered at a dosage of three times the recommended. If suspected toxic reactions do occur due to extreme overdosage, appropriate symptomatic treatment should be performed if necessary.

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

Any unused product or waste material should be disposed of in accordance with national requirements. The product cannot be released into natural waters.

**14. DATE OF LAST REVISION OF SPC**

18 December 2012

**15. ADDITIONAL INFORMATION**

**Nature and contents of container:**

Primary container: 2 tablets in strip packs of polyethylene/aluminium foil.

Secondary container: carton box, contents: 5x2 tablets in each box.

**Registration number**

3275/1/12 NÉBIH ÁTI (5x2 tablets)

With additional questions about the product please turn directly to the manufacturing authorisation holder or its nominee.

**Conditions or restrictions regarding supply and use**

Over-the-counter. For animal treatment only.