

SUMMARY of PRODUCT CHARACTERISTICS (SPC)

1. Name of the veterinary medicinal product

Cestral Plus flavour tablets ad us. vet.

active substances:

praziquantel
pyrantel pamoate
fenbendazole

2. Qualitative and quantitative composition

Each tablet contains:

Active substances

Praziquantel	50.0 mg
Pyrantel pamoate	144.0 mg
Fenbendazole	200.0 mg

Excipients

Lactose monohydrate, wheat starch, povidone, talc, magnesium stearate, sodium starch glycolate, liver flavour

3. Pharmaceutical form

Tablet for oral administration.

4. Pharmacological properties

Pharmacotherapeutic group: quinolone derivatives. ATCvet Code: QP52AA51.

Cestral Plus is a broad-spectrum anthelmintic containing praziquantel, pyrantel pamoate and fenbendazole as active substances. It exhibits a high activity against all common tapeworms and roundworms of dogs also including several immature forms. Of the active ingredients, praziquantel is the most effective cestocidal agent used in the human and veterinary practice having 100% activity against *Echinococcus granulosus*, as well. Pyrantel pamoate is known to be highly effective for the common ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*) of dogs at single oral doses of 5 mg base per kg of body weight, with only limited activity, however, against canine whipworms (*Trichuris vulpis*). In order to be effective against whipworms as well, Cestral Plus contains the benzimidazole compound, fenbendazole which is active against *Trichuris* and exhibits, moreover, a specific synergy with pyrantel pamoate against nematodes. According to the target animal safety tests, Cestral Plus tablets possess a high margin of safety, no adverse reactions were observed even at a fivefold level.

5. Clinical particulars

5.1. Target species

Dog.

5.2. Indications for use

Cestral Plus is recommended for the treatment and control of all common tapeworm and roundworm infestation of dogs and puppies including:

- * tapeworms: *Echinococcus species*, *Taenia species*, *Dipylidium caninum*
(adults and immature forms)
- * ascarids: *Toxocara canis*, *Toxascaris leonina*
(adult and immature forms)
- * hookworms: *Ancylostoma caninum*, *Uncinaria stenocephala*
- * whipworms: *Trichuris vulpis*

5.3. 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. The product is not recommended for treatment under 4 weeks of age.

5.4. Undesirable effects

Acute toxicity of the product is >2000 mg/kg. Cestral Plus is of low toxicity having a high margin of safety. During the target animal safety tests no clinical, hematological or biochemical adverse reactions were detected when the product was administered at the fivefold dose level. The clinical studies also failed to reveal any undesirable effect.

5.5. Special precautions for use

No special precautions are required.

5.6. Use during pregnancy

The product can also be safely administered to pregnant bitches.

5.7. 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 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.

5.8. Posology and method of administration

Dosage: one tablet per 10 kg of body weight

Puppies and small dogs:

< 2 kg b.w. = 1/4 tablet

2-5 kg b.w. = 1/2 tablet

5-10 kg b.w. = 1 tablet

Medium dogs:

10-20 kg b.w. = 2 tablets

20-30 kg b.w. = 3 tablets

Large dogs:

30-40 kg b.w. = 4 tablets

40-50 kg b.w. = 5 tablets and pro rata.

Method of administration:

For oral use only. The tablets can be given directly to the mouth or disguised in food (a piece of meat, sausage, etc.). Prior to administration no starvation or specific feeding regime is needed. 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 months.

5.9. Overdose

Overdosage of Cestel Plus tablets in the clinical practice may very rarely occur because of good tolerance by the target species to be used in. If suspected toxic reactions do occur due to extreme overdosage, appropriate symptomatic treatment should be performed if necessary.

5.10. Special warnings for each target species

Nil.

5.11. Withdrawal periods

No food producing animals can be treated with the product.

5.12. Special safety precautions to be taken by the person administering the product to 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 wash hands after cleaning. After treatment keep the children away for a few days.

6. Pharmaceuticals particulars

6.1. Major incompatibilities

Nil.

6.2. Shelf-life

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

6.3. Special precautions for storage

Store in original foil pack between 15 and 25°C. Protect from light.

6.4. Nature and contents of container

Primary container: strip packs of polyethylene/aluminium foil.

Secondary container: paper box.

Contents: 5X2 tablets in each box.

100X2 tablets in each box.

6.5. Special precautions for the disposal of unused product or waste materials

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

6.6. Name or style and permanent address of registered place of business of the marketing authorisation holder

LAVET Ltd. (1161 Budapest, Ottó utca 14.)

6.6. Conditions or restrictions regarding supply and use

Veterinary medicinal product subject to prescription. For animal treatment only.

Marketing Authorisation Number: 645/1997 FVM

7. Additional information

7.1. First approval/renewal of the SPC

16 February 1998/6 October 2005

7.2. Date of last revision of SPC

23 June 2006

I. B 2. PROPOSALS for LABELLING and PACKAGE INSERT

A. Labelling

A1. Particulars to appear on the outer package

Paperbox

5X2 tablets / box

100X2 tablets / box

1. NAME of the VETERINARY MEDICINAL PRODUCT

Cestral Plus Flavour Tablets

2. STATEMENT of ACTIVE SUBSTANCES

Each tablet contains:

Active substances

Praziquantel	50.0 mg
Pyrantel pamoate	144.0 mg
Fenbendazole	200.0 mg

Excipients

Lactose monohydrate, wheat starch, povidone, talc, magnesium stearate, sodium starch glycolate, liver flavour

3. PHARMACEUTICAL FORM

Tablet for oral administration.

4. PACKAGE SIZE

- (i) 5X2 tablets per box.
- (ii) 100X2 tablets per box.

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Cestral Plus is recommended for the treatment and control of all common tapeworm and roundworm infestation of dogs and puppies including:

- tapeworms: *Echinococcus species, Taenia species, Dipylidium caninum*
(adults and immature forms)
- ascarids: *Toxocara canis, Toxascaris leonina*
(adult and immature forms)
- hookworms: *Ancylostoma caninum, Uncinaria stenocephala*
- whipworms: *Trichuris vulpis*

7. METHOD and ROUTE(S) of ADMINISTRATION

Dosage: one tablet per 10 kg of body weight

Puppies and small dogs:

- < 2 kg b.w. = 1/4 tablet
- 2-5 kg b.w. = 1/2 tablet
- 5-10 kg b.w. = 1 tablet

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8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS

Read the package insert before use.

The product is not recommended for treatment under 4 weeks of age.

Do not use simultaneously with piperazine, morantel, levamisole, diethylcarbamasine and organophosphate compounds.

Cestral Plus Flavour - angol SPC ÁOGYTI forma - 2007.02.

Accidental swallowing maybe harmful – see package insert for more information.
The general labour safety precautions must be observed.

10. EXPIRY DATE

Expiry date: month/year 00/0000

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25°C. Store in a dry place.

12. SPECIAL PRECAUTIONS for the DISPOSAL of UNUSED VETERINARY MEDICINAL PRODUCTS or WASTE MATERIALS DERIVED from SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

13. THE WORDS „FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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.
1161 Budapest
Ottó u. 14.
Hungary

16. REGISTRATION NUMBER

645/1997 FVM

17. MANUFACTURER’S BATCH NUMBER

18. CONDITIONS or RESTRICTIONS regarding SUPPLY and USE

Veterinary medicinal product subject to prescription.

A2. Particulars to appear on strip packs

1. NAME of the VETERINARY MEDICINAL PRODUCT

Cestal Plus Flavour Tablets

2. NAME AND PERMANENT ADDRESS OF REGISTERED PLACE OF BUSINESS OF THE MARKETING AUTHORISATION HOLDER

LAVET Ltd. (1161 Budapest, Ottó utca 14.)

3. EXPIRY DATE

(month/year 00/0000)

4. BATCH NUMBER

Batch number

B. Package insert

1. NAME of the VETERINARY MEDICINAL PRODUCT

Cestal Plus Flavour Tablets

2. STATEMENT of ACTIVE SUBSTANCES

Each tablet contains:

Active substances

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Excipients

Lactose monohydrate, wheat starch, povidone, talc, magnesium stearate, sodium starch glycolate, liver flavour

3. NAME and ADDRESS of the MARKETING AUTHORISATION HOLDER and of the MANUFACTURING AUTHORISATION HOLDER

LAVET Pharmaceuticals Ltd.

1161 Budapest

Ottó u. 14.

Hungary

4. TARGET SPECIES

Dogs.

5. INDICATIONS

Cestal Plus is recommended for the treatment and control of all common tapeworm and roundworm infestation of dogs and puppies including:

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(adults and immature forms)
- ascarids: *Toxocara canis, Toxascaris leonina*
(adult and immature forms)
- hookworms: *Ancylostoma caninum, Uncinaria stenocephala*
- whipworms: *Trichuris vulpis*

6. DOSAGE for SPECIES

Dosage: 1 tablet/10 kg of body weight

Puppies and small dogs:

< 2 kg b.w. = 1/4 tablet

2-5 kg b.w. = 1/2 tablet

5-10 kg b.w. = 1 tablet

Medium dogs:

10-20 kg b.w. = 2 tablets

20-30 kg b.w. = 3 tablets

Large dogs:

30-40 kg b.w. = 4 tablets

40-50 kg b.w. = 5 tablets and pro rata.

7. METHOD and ROUTE(S) of ADMINISTRATION

For oral use. Prior to administration no starvation or specific feeding regime is needed.

8. ADVICE on CORRECT ADMINISTRATION

The tablets can be given directly to the mouth or disguised in food (a piece of meat, sausage, etc.). Treatment 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. The product can also be safely administered to pregnant bitches.

9. 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. The product is not recommended for treatment under 4 weeks of age.

10. UNDESIRABLE EFFECTS

Acute toxicity of the product is >2000 mg/kg. Cestal Plus is of low toxicity having a high margin of safety. During the target animal safety tests no clinical, hematological or biochemical adverse reactions were detected when the product was administered at the fivefold dose level. The clinical studies also failed to reveal any undesirable effect. If side effects are seen please report to your veterinarian immediately.

11. WITHDRAWAL PERIOD

No food producing animals can be treated with the product.

12. SPECIAL STORAGE CONDITIONS

Keep out of reach of children.

Store between 15 and 25°C. Protect from light.

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

The product can only be used within the shelf-life period indicated on the box.

13. SPECIAL WARNINGS

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 diethylcarbamazine. Because of the similar mechanism of action and toxicology it is also advised to avoid the co-administration with morantel and levamisol.

Overdose

Overdose of Cestral Plus Flavour in the clinical practice may rarely occur because of good tolerance by the target species to be used in. If suspected toxic reactions do occur due to extreme overdosage, appropriate symptomatic treatment should be performed if necessary.

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 dogs for a few days.

14. SPECIAL PRECAUTIONS for the DISPOSAL of UNUSED VETERINARY MEDICINAL PRODUCTS or WASTE MATERIALS DERIVED from SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

15. DATE on which the PACKAGE INSERT WAS LAST REVISED

23 June 2006

16. OTHER INFORMATION

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

16.1. CONDITIONS or RESTRICTIONS regarding SUPPLY and USE

Veterinary medicinal product subject to prescription. For animal treatment only.

16.2. CONDITIONS or RESTRICTIONS regarding DISTRIBUTION

Veterinary medicinal product subject to sell only by authorised distributors.

16.3. NATURE AND CONTENTS OF CONTAINER

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

Secondary container: carton box, contents: 5X2 tablets/box, 100X2 tablets/box.

16.4. REGISTRATION NUMBER

645/1997 FVM