

SUMMARY of PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

HELM-EX Flavour Tablets

2. Qualitative and quantitative composition

Each tablet contains:

Active substances

Praziquantel	50.0 mg
Pyrantel embonate	144.0 mg

Excipients

Lactose monohydrate, wheat starch, povidone, talc, magnesium stearate, dried yeast, liver flavour

3. Pharmaceutical form

Tablet.

4. Clinical particulars

4.1. Target species

Dog.

4.2. Indications for use

HELM-EX is recommended for the treatment and control of the common tapeworm and roundworm infestations of dogs and puppies caused by:

* ascarids: *Toxocara canis*, *Toxascaris leonina*
(adult and late immature forms)

* hookworms: *Ancylostoma caninum*, *Uncinaria stenocephala*
(adult)

* tapeworms: *Echinococcus species*, *Taenia species*, *Dipylidium caninum*
(adults and immature forms)

4.3. Contra-indications

It should not be used in dogs exhibiting previous hypersensitivity to any of the active substances or excipients of the product. The use of the product is not recommended under 4 weeks of age.

4.4. Special warnings for each target species

Nil.

4.5. Special precautions for use

Special precautions for us in animals

No special precautions are required.

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

Wash hands after use.

4.6. Undesirable effects

HELM-EX is of low toxicity having a high margin of safety. During the target animal safety tests no clinical 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.

4.7. Use during pregnancy, lactation

The product can also be safely administered to pregnant bitches.

4.8. 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.

No other interactions are known. Prior to administration no starvation or specific feeding regime is needed.

4.9. Posology and method of administration

Dosage: one tablet per 10 kg of body weight which corresponds to the following dose rates of the active substances:

* praziquantel 5 mg/kg

* pyrantel base 5 mg/kg

For routine worming of dogs only a single treatment is necessary. This should be repeated every 3 months for routine worm control. In the event of heavy roundworm infestation a repeat dose may be given after 14 days.

Administration: oral use.

The tablets can be given directly to the dog or disguised in food. Treatment immediately prior to feeding is recommended.

4.10. Overdose

Overdosage of HELM-EX Flavour tablets in the clinical practice may very 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 five 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

Not applicable.

5. Pharmacological properties

Pharmacotherapeutic group: quinolone derivatives; ATCvet code: QP52AA51. HELM-EX is a broad-spectrum anthelmintic containing praziquantel and pyrantel embonate as active substances. It exhibits a high activity against the 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 an excellent activity against *Echinococcus granulosus*, as well. Pyrantel embonate 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. According to the target animal safety tests, HELM-EX possesses a high margin of safety.

6. Pharmaceuticals particulars

6.1. List of excipients

Lactose monohydrate
Wheat starch
Povidone
Talc
Magnesium stearate
Dried yeast
Liver flavour

6.2. Incompatibilities

None known.

6.3. Shelf-life

2 years.

6.4. Special precautions for storage

Store in a dry place between 15-25°C.

Keep out of the reach and sight of children.

6.5. Nature and contents of container

Primary container: strip packs of polyethylene/aluminium foil.

Secondary container: carton box.

Contents: 5x2 tablets in carton box

6.6. Special precautions for the disposal of unused medicinal product or waste materials derived from such medicinal products , if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.

1161 Budapest

Ottó u. 14.

Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING

1. NAME of the VETERINARY MEDICINAL PRODUCT

HELM-EX Flavour Tablets

2. STATEMENT of ACTIVE SUBSTANCES

Each tablet contains:

Active substances:

Praziquantel 50 mg/tablet
Pyrantel embonate 144 mg/tablet

Relevant excipients:

None.

3. PHARMACEUTICAL FORM

Tablet for oral administration.

4. PACKAGE SIZE

5x2 tablets in carton box

5. TARGET SPECIES

Dogs.

6. INDICATIONS

For treatment and control of cestode and nematode infestations of dogs as follows:

- Tapeworms: *Echinococcus* sp., *Taenia* sp., *Dipylidium caninum*
- Ascarids: *Toxocara canis*, *Toxascaris leonina*
(adults and late immature forms)
- Hookworms: *Ancylostoma caninum*, *Uncinaria stenocephala*

7. METHOD and ROUTE(S) of ADMINISTRATION

For oral use.

Dosage: 1 tablet/10 kg of bodyweight.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS

Do not use simultaneously with piperazine compounds.

10. EXPIRY DATE

2 years.

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

13. THE WORDS „FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of reach and sight children.

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

LAVET Pharmaceuticals Ltd.

1161 Budapest

Ottó u. 14.

Hungary

16. MANUFACTURER’S BATCH NUMBER

Particulars to appear on strip packs

1. NAME of the VETERINARY MEDICINAL PRODUCT

HELM-EX Flavour Tablets

2. NAME OF THE MARKETING AUTHORIZATION HOLDER

LAVET Pharmaceuticals Ltd.

3. EXPIRY DATE

(month/year)

4. BATCH NUMBER

5. THE WORDS „FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE INSERT

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

Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary

2. NAME of the VETERINARY MEDICINAL PRODUCT

HELM-EX Flavour Tablets

3. STATEMENT of ACTIVE SUBSTANCES

Each tablet contains:

Active substances:

Praziquantel	50 mg/tablet
Pyrantel embonate	144 mg/tablet

4. INDICATIONS

For treatment and control of cestode and nematode infestations of dogs caused by parasites as follows:

- Tapeworms: *Echinococcus* sp., *Taenia* sp., *Dipylidium caninum*
- Ascarids: *Toxocara canis*, *Toxascaris leonina* (adults and late immature forms)
- Hookworms: *Ancylostoma caninum*, *Uncinaria stenocephala*

5. CONTRA-INDICATIONS

It should not be used in dogs exhibiting hypersensitivity to any of the active substances or the excipients.

6. ADVERSE REACTIONS

None known.

7. TARGET SPECIES

Dogs.

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

Dosage: 1 tablet/10 kg of body weight

Method of administration: for oral use

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.

For routine worming of dogs only a single treatment is necessary. This should be repeated every 3 months for routine worm control. In the event of heavy roundworm infestation a repeat dose may be given after 14 days.

9. ADVICE on CORRECT ADMINISTRATION

The tablets can be given directly to dogs or disguised in food. No starvation or specific feeding regime is needed. Treatment prior to feeding is recommended.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL WARNINGS

Do not use simultaneously with piperazine compounds.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size: 5x2 tablets.

For routine worming of dogs only a single treatment is necessary. This should be repeated every 3 months for routine worm control. In the event of heavy roundworm infestation a repeat dose may be given after 14 days.