ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1x2 tablets, 2x2 tablets, 52x2 tablets, 1x8 tablets, 3x8 tablets, 6x8 tablets, 13x8 tablets, 5x2 tablets or 25x2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Helmex Cat 80 mg/20 mg Chewable Tablets for

Praziquantel
Pyrantel embonate

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances

Praziquantel	20 mg
Pyrantel	80 mg, equivalent to 230 mg Pyrantel embonate

3. PHARMACEUTICAL FORM

Chewable tablet.

4. PACKAGE SIZE

1x2 tablets
2x2 tablets
52x2 tablets
1x8 tablets
3x8 tablets
6x8 tablets
13x8 tablets
5x2 tablets
25x2 tablets

5. TARGET SPECIES

Cats.

6. INDICATION(S)

For the treatment of mixed infestations with tapeworms and roundworms in cats caused by the following parasites:
- roundworms: *Toxocara mystax (cati)*, *Toxascaris leonina* (adult and late immature forms)
- hookworms: *Ancylostoma tubaeforme*,
- tapeworms: *Echinococcus multilocularis*, *Hydatigena (Taenia) taeniaeformis*, *Dipylidium caninum* (adults and immature forms), *Joyeuxiella* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}
Tablet halves should be used at the next administration time.
Shelf life of the divided (halved) tablets after opening the blister: 2 days.

11. SPECIAL STORAGE CONDITIONS

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

Any unused product or waste materials derived from this product should be disposed of in accordance with local requirements.

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

Zylavet Pharmaceuticals Ltd
H-2143 Kistarcsa
Batthyany u.6
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44020/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTER OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Helmex Cat 80 mg/20 mg Chewable Tablets for Cats

Praziquantel
Pyrantel embonate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

ZYLAVET Pharmaceuticals Ltd.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cestal/ Helmex Cat 80/20 mg Chewable Tablets for Cats

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

Marketing authorisation holder:
Zylavet Pharmaceuticals Ltd., Kistarcsa, 2143 Batthyány u. 6., Hungary

Manufacturer responsible for batch release: Lavet Pharmaceuticals Ltd., Kistarcsa, 2143 Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cestal Cat 80/20 mg chewable tablets for cats (in Bulgaria, Cyprus, Hungary, Estonia, Latvia, Lithuania, Netherlands, Poland, Romania, Slovakia, Poland and Czech Republic)

Helmex Cat 80 mg/20 mg Chewable Tablets for Cats (in France, Ireland and United Kingdom)

Praziquantel
Pyrantel embonate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:
Active substances

Praziquantel	20 mg
Pyrantel	80 mg, equivalent to 230 mg Pyrantel embonate

Yellowish - brownish oval tablet with a scoring line.
Each tablet can be divided into 2 equal parts.

4. INDICATION(S)

For the treatment of mixed infestation with tapeworms and roundworms in cats caused by the following parasites:
- roundworms: *Toxocara cati*, *Toxascaris leonina* (adult and late immature forms)
- hookworms: *Ancylostoma tubaeforme*,
- tapeworms: *Echinococcus multilocularis*, *Hydatigena (Taenia) taeniaeformis*, *Dipylidium caninum* (adults and immature forms), *Joyeuxiella* spp.

5. CONTRAINDICATIONS

The product cannot be used in case of allergy to the active ingredients or any of the excipients. Not intended for use in kittens under 6 weeks of age. Do not use simultaneously with piperazine compounds.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur. 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

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).

- Bodyweight of at least 1 kg, up to a maximum of 2 kg: ½ tablet
- Bodyweight of greater than 2 kg, up to a maximum of 4 kg: 1 tablet
- Bodyweight of greater than 4 kg, up to a maximum of 6 kg:1½ tablets
- Bodyweight of greater than 6 kg, up to a maximum of 8 kg: 2 tablets

9. ADVICE ON CORRECT ADMINISTRATION

Single oral administration.
Administration and Duration of Treatment
The chewable tablets can be administered directly into the mouth of the cat or disguised in food (a piece of meat, sausage, etc.). In roundworm infections, especially in young animals, a complete elimination cannot be expected and a risk to humans remains.
In a study conducted in 30 cats, there was voluntary consumption on 83% of occasions.
No restriction of access to food is required either before or after administration of the product. To ensure administration of a correct dose, body weight should be determined as accurately as possible.
The advice of a veterinarian should be sought regarding the need for and frequency of repeat treatment.

10. WITHDRAWAL PERIOD

Non applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Each time an unused half tablet is stored, it should be returned to the open blister or strip space and inserted back into the cardboard box.
Shelf life of the divided (halved) tablets after opening the blister: 2 days.

12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the interests of good hygiene, persons administering the tablets directly to a cat or by adding them to the cat's food should wash their hands afterwards.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Echinococcosis represents a hazard for humans. As echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of people, need to be obtained from the relevant competent authority

Special precautions for use in animals:
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

Pregnancy and lactation:
Do not use in pregnancy. The product can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine compounds..

Overdose (symptoms, emergency procedures, antidotes):
Symptoms of overdose do not occur at up to 5 times the recommended dose. After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

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

Any unused product or waste materials derived from this product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Nature and contents of container:
Product is packaged into either cold formed foil blisters consisting of a composite aluminium strip with a heat sealed aluminium film or strip packs made of multiple laminate of aluminium foil/polyethylene.

- Box containing 1 blister strip of 2 tablets
- Box containing 2 blister strips of 2 tablets
- Box containing 52 blister strips of 2 tablets
- Box containing 1 blister strip of 8 tablets
- Box containing 3 blister strip of 8 tablets
- Box containing 6 blister strips of 8 tablets
- Box containing 13 blister strips of 8 tablets

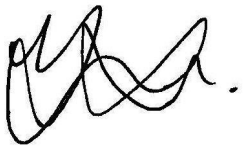
- Box containing 5 strip packs of 2 tablets
- Box containing 25 strip packs of 2 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Conditions or restrictions regarding supply and use

For animal treatment only.



Approved: 17 October 2019