SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Helmex Cat 80 mg/20 mg Chewable Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substances:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of mixed infestations 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.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or any of the excipients. Do not use in kittens less than 6 weeks of age. Do not use concomitantly with piperazine compounds. Please see section 4.7.

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas and mice is undertaken. Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

4.5 Special precautions for use

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.
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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy. Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amounts to be administered and administration route

Dosage
The recommended dose rates are: 20.0 mg pyrantel (equivalent 57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg body weight.

Body weight (kg)	*Number of tablets*
≥1.0 - ≤2.0	½
>2.0 - ≤4.0	1
>4.0 - ≤6.0	1 ½
>6.0 - ≤8.0	2

Administration and Duration of Treatment
Single oral administration. The chewable tablet should be given directly to the animal, but if necessary can be disguised in food.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, quinolone derivatives and relative substances, praziquantel combinations.
ATC vet code: QP52AA51.

5.1 Pharmacodynamic properties

Praziquantel is very rapidly absorbed into and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.
Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow expulsion from the gastrointestinal (GI) system by peristalsis.

5.2 Pharmacokinetic particulars

Praziquantel is rapidly absorbed, metabolised and distributed in the body. Following oral administration to cats, peak plasma concentrations were achieved by approximately 2 hours. Praziquantel is metabolised in the liver. It is completely excreted, primarily in the form of metabolites in the urine, within 48 hours of administration.

Pyrantel is poorly absorbed, so it is expected that a large proportion of the administered dose remains in the gastrointestinal tract, where it exerts its therapeutic effect. It is excreted largely unchanged in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl palmitate
Lactose monohydrate
Starch, pregelatinised
Sodium starch glycolate type A
Dried yeast
Pork liver powder
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of the divided (halved) tablets after opening the blister: 2 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions. Use any divided tablet at the next administration time, which should not exceed 48 hours. Each time an unused half tablet is stored it should be returned to the open blister or strip space and inserted back into the folding box and kept in a safe place out of the reach of children.

6.5 Nature and composition of immediate packaging

The product is packaged into either blisters consisting of a composite aluminium foil with a heat sealed aluminium film or strip made of multiple laminate of aluminium foil/polyethylene.

- Box containing 1 blister of 2 tablets (2 tablets)
- Box containing 2 blister of 2 tablets (4 tablets)
- Box containing 52 blister of 2 tablets (104 tablets)
- Box containing 1 blister of 8 tablets (8 tablets)
- Box containing 3 blister of 8 tablets (24 tablets)
- Box containing 6 blister of 8 tablets (48 tablets)
- Box containing 13 blister of 8 tablets (104 tablets)
- Box containing 5 strip of 2 tablets (10 tablets)
- Box containing 25 strip of 2 tablets (50 tablets)

Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION HOLDER

Zylavet Pharmaceuticals Ltd

H-2143 Kistarcsa
Batthyany u.6
Hungary

8. MARKETING AUTHORISATION NUMBER

Vm 44020/4004

9. DATE OF FIRST AUTHORISATION

2 June 2017

10. DATE OF REVISION OF THE TEXT

October 2019

Approved: 17 October 2019