[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerocit 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Praziquantel 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Silica, colloidal Anhydrous
Maize Starch
Povidone K-30
Isopropyl Alcohol
Purified Water
Sodium Lauryl Sulfate
Magnesium Stearate

White round tablet scored on one side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of infections with cestodes of the following species: *E. granulosus, E. multilocularis, T. hydatigena, T. pisiformis, T. ovis, T. taeniaeformis, T. multiceps, Mesocestoides spp. and Dipylidium caninum*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm: *Dipylidium caninum*. Tapeworm infestation will surely recur unless control of intermediate hosts is implemented (fleas, mice, etc.).

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should

be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each group of animals.

The parasite resistance to a particular class of anthelmintic may develop using such an anthelmintic frequently and repeatedly.

The possibility that other animals in the same household can be a source of re-infection with should be considered.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g., faecal egg count reduction (FECR) method)

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash your hands after administering the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Echinococcosis represents a hazard for humans. As echinococcosis is a notifiable disease to the World Organisation for Animal Health, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anorexia, lethargy, diarrhoea and vomiting.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder, its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Contraindications have not been described during these periods.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 5 mg of praziquantel per kg of bodyweight. This equals to 1 tablet per 10 kg of bodyweight in a single dose.

2.5 – 5 kg	½ tablet
>5 – 10 kg	1 tablet
>10 – 20 kg	2 tablets
>20 – 30 kg	3 tablets
>30 – 40 kg	4 tablets, etc

It can be administered directly to animals or crushed and mixed with food.

Repeat treatment should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

If *Echinococcus* spp. infestation is detected, it is recommended to repeat treatment for safety reasons.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Praziquantel is well tolerated with a wide safety margin. Doses higher than recommended may cause vomiting.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AA01

4.2 Pharmacodynamics

Praziquantel is an internal antiparasitic with cestocidal activity, which alters the integument of the parasite making it permeable to excessive glucose loss and facilitating the attack of the proteolytic enzymes. In addition, it interferes with contractility mechanisms and transport of regulatory ions through the myofibrils of the parasite. This fact causes a spasticity paralysis that affects the motility and the anchoring organs of the cestode (induces spasticity paralysis of the parasite by interfering with the contractility mechanisms as well as the transport of regulating ions through the microfibrils of the parasite).

4.3 Pharmacokinetics

Praziquantel is absorbed in the small intestine, reaching maximum concentration at 30-60 minutes following administration. The action against the cestodes occurs as consequence of the presence of the drug in the intestine and, as a result of re-excretion of the drug through the intestinal cells (for this reason it affects the head or scolex of the flatworm).

Praziquantel is metabolized in the liver and rapidly excreted as metabolite through urine and bile.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after splitting tablet: use immediately.

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Silver aluminium/aluminium blisters.

Pack sizes:
Carton containing 2 blisters of 10 tablets (20 tablets).
Carton containing 4 blisters of 10 tablets (40 tablets).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Cyton AH Biosciences GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

ES: Veterinary medicinal product subject to prescription.
HU:
IE: Veterinary medicinal product not subject to prescription.
IT: Veterinary medicinal product not subject to prescription.
NL: Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).