ANNEX III

LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zerocit 50 mg tablets for dogs

2. Composition

Each tablet contains:
Praziquantel 50 mg

White round tablet scored on one side.

3. Target species

Dogs.

4. Indications for use

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*.

5. Contraindications

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

6. Special warnings

This veterinary medicinal product does not contain any antimicrobial preservatives.

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.

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.

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.

Pregnancy and lactation:

Contraindications have not been described during these periods.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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

Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

Major incompatibilities:

None known.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}.

8. Dosage for each species, routes and method of administration

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

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.

9. Advice on correct administration

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

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after splitting tablet: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. 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.

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder:
Cyton AH Biosciences GmbH
Konrad-Zuse-Ring 25
68163 Mannheim
Germany

Manufacturer responsible for batch release:
Pantex Holland B.V.
Samaragdweg 15
5527 LA Hapret
The Netherlands

<Local representatives <and contact details to report suspected adverse reactions>:>

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

17. Other information>