1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit Tablets 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Praziquantel 50.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline Cellulose
Povidone K-25
Sodium Lauryl Sulphate
Magnesium Stearate
Silica Colloidal Anhydrous
Maize Starch

White round tablet scored on one side, which can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

For the treatment of adult tapeworms. The tablets are effective against both immature and mature forms of adult tapeworms in both dogs and cats.
The veterinary medicinal product is a highly effective treatment against all the common species of tapeworm infecting dogs and cats in the United Kingdom and Ireland including *Echinococcus granulosus*, *Taenia ovis, Taenia pisiformis, Taenia multiceps, Taenia hydatigena, Taenia taeniaeformis,* and *Dipylidium caninum.* The veterinary medicinal product is also effective against *Echinococcus multilocularis* (see 3.4).

3.3 Contraindications

Do not use in dogs weighing less than 2.5 kg.
Do not use in unweaned puppies and kittens, as such animals are rarely infected with tapeworms.

3.4 Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm-*Dipylidium caninum*. To avoid reinfection with this parasite, flea control of the animal and its housing should be carried out at the same time. Unless flea control is complete an infected flea population may survive: i.e. re-treatment of the animal may be necessary.

As a precautionary measure to prevent establishment of *Echinococcus multilocularis* in Ireland it is recommended that all dogs entering the country be treated with praziquantel.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Any part used tablets should be discarded.

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 an animal or adding them to the animal's food should wash their hands afterwards.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs and Cats
None known.

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 or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Dosage

The recommended dosage rate is 5 mg/kg body weight. This corresponds to 1 tablet per 10 kg body weight.

Dogs	Greater than 2.5 to 5.0 kg	½ tablet
	Greater than 5.0 to 10.0 kg	1 tablet
	Greater than 10 to 15kg	1 ½ tablets
	Greater than 15 to 20 kg	2 tablets
	Greater than 20 to 25 kg	2 ½ tablets
	Greater than 25 to 30 kg	3 tablets
	Over 30kg *pro rata*	For each additional 5kg bodyweight, administer an additional half tablet

Cats	Adult cats	½ tablet

Administration and Duration of Treatment

The tablets are administered by opening the animal's mouth and pushing the tablet over the back of the tongue so that it cannot be rejected. Alternatively, a tablet can be wrapped in a piece of meat or butter and offered to the animal or crushed and mixed with the food.

A single dose is all that is required. However, for dogs in rural areas and for packs of hounds, this dose should be repeated every four weeks to ensure that newly acquired tapeworms are destroyed before reaching maturity. Dosing must be associated with strict control of the dog's diet to ensure that uncooked offal is not eaten.

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

Not applicable.

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.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP52AA01

4.2 Pharmacodynamics

The spectrum of action of praziquantel covers all the important species of cestodes in dogs and cats. It specifically includes all *Taenia*species occurring in dogs and cats, *Multiceps multiceps*, *Joyeuxiella pasquali*, *Dipylidium caninum, Mesocestoides*species, *Echinococcus multilocularis and E.granulosus.* Praziquantel is effective against all stages of development of these parasites occurring in the intestines of dogs and cats.

Praziquantel impairs the normal tegument function of the parasite, making it permeable to excessive glucose loss and thereby more easily attacked by proteolytic enzymes. Because of this, whole tapeworms including the scolex are very rarely passed in the faeces following administration of the drug. Disintegrated and partially digested fragments may occasionally be seen in the faeces.

4.3 Pharmacokinetics

Praziquantel is rapidly absorbed by the animal and metabolised by the liver. It is excreted, entirely as metabolites, in the urine and faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

Do not store above 25 ϟC.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Container material:

Aluminium foil blister or polyethylene-coated aluminium blister. Container colour:
Silver or white coloured.

Pack sizes:

Cartons containing 2 x 10 tablet blisters, 3 x 8 tablet blisters, 6 x 8 tablet blisters, 10 x 10 tablet blisters or 13 x 8 tablet blisters.

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

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/005/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

07/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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).