Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit Tablets 50 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Praziquantel 50.0 mg per tablet

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
White round tablet scored on one side.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of adult tapeworms of dogs and cats. The tablets are effective against both immature and mature forms of adult tapeworms in both dogs and cats.
The 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*. Droncit is also effective against *Echinococcus multilocularis* (see 4.4).

4.3 Contraindications

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

4.4 Special warnings for each target species

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 *Echinococcusmultilocularis*in the UK and Ireland it is recommended that all dogs entering the country be treated with praziquantel.

4.5 Special precautions for use

Special precaution for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be administered to pregnant females. It is safe to the female herself, to the unborn foetus and to the new-born young.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Dosage

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

Dogs:

2.5 - 5.0 kg ½ tablet
6.0 - 10.0 kg 1 tablet
11 - 20 kg 2 tablets
21 - 30 kg 3 tablets

Over 30 kg *pro rata*

Cats:

Adults ½ tablet

Administration and Duration of Treatment

Oral administration.

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.

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

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Praziquantel is a pyrazino-isoquinolin derivative, with anthelmintic activity.
ATC VetCode: QP52AA01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline Cellulose
Povidone K-25
Sodium Lauryl Sulphate
Magnesium Stearate
Silica Colloidal AnhydrousMaize Starch

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10521/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 12 June 2009

10 DATE OF REVISION OF THE TEXT

November 2022