SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit® Solution for Injection 5.68%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active Constituents	% w/v
Praziquantel	5.68

2.2 Relevant Constituents of the Excipients

Benzyl alcohol	7.50
Chlorobutanol	0.50

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Colourless to pink yellowish liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

For the removal of all intestinal stages (mature and immature) of the following canine and feline parasites :

Echinococcus granulosus, Taenia pisiformis, Taenia taeniaeformis and *Dipylidium caninum.*

4.3 Contraindications

Should not be administered to unweaned puppies and kittens, as such animals are rarely infected with tapeworms.
Not recommended in hounds.

4.4 Special warnings for each target species

Slight local sensitivity may follow subcutaneous injection of large doses in heavy dogs.
Subcutaneous injection of cats in the scruff of the neck may also cause local sensitivity leading to self-inflicted trauma. A subcutaneous site over the ribs, behind the elbow is to be preferred.
It is recommended that show cats or cats with a history of such sensitivity should be treated by the oral route using tablets.

4.5 Special precautions for use

i) Special precautions for use in animals

Care should be taken to avoid intradermal or perineural injection.
Use aseptic technique (see also 4.9 and 4.5.i).
Use a dry, sterile needle and syringe.

ii) Special precautions to be taken by the person administering the medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy and lactation

Use of praziquantel has been shown to be safe during pregnancy for the dam, the unborn foetus and the new-born young. There is no information, however, on the use of this *formulation* during pregnancy and lactation. Should treatment at this time be required, it is recommended that administration by the oral route with tablets be considered.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amount(s) to be administered and administration route

Dosage

The recommended dosage rate is 0.1 ml/kg body weight (1 ml per 10 kg bodyweight).
The minimum effective dose of praziquantel varies from 3.5 to 7.5 mg/kg bodyweight. Smaller animals require relatively larger doses because of their higher metabolic rate.

Dogs and Puppies

Under 2.5 kg	0.25 ml
2.5 - 5.0 kg	0.50 ml
6.0 - 10 kg	1.00 ml
11 - 20 kg	2.00 ml*
21 - 30 kg	3.00 ml**

* Use 0.2 ml/2.5 kg bodyweight over 12 kg

**Maximum s.c. dose at one site is 3.0 ml

Cats and Kittens

Under 1.0 kg	0.1 ml
1.0 - 2.0 kg	0.2 ml
2.0 - 3.0 kg	0.3 ml
3.0 - 4.0 kg	0.4 ml
4.0 - 5.0 kg	0.5 ml
Over 5 kg	0.6 ml

An appropriately graduated syringe must be used to allow administration of the required dose volume. This is particularly important when administering small dose volumes.

Administration and Duration of Treatment

May be administered by either the subcutaneous or the intramuscular route for both cats and dogs. The intramuscular route may be preferred in dogs weighing over 23 kg. A brief period of pain occasionally follows subcutaneous administration. If a dose over 3 ml must be given subcutaneously it should always be divided and applied to two different sites. The intramuscular route is preferred whenever *Echinococcus* is suspected. Injection should be made with care to avoid intradermal administration and perineural injection. Recommended sites are behind the elbow, over the ribs (sc) and into the quadriceps femoris (im).

For those animals maintained on premises where re-infections are likely to occur, steps should be taken to prevent re-infection. If the measures adopted are not adequate a second course of treatment may be necessary. This is particularly true of dogs in rural environments and owners should be advised not to feed raw meat, offal or heads.

In cases of *Dipylidium caninum* infection, re-infection is almost certain to occur if fleas are not removed from the patient's environment. Flea control of the animal and its housing should be carried out at the same time as it is treated for cestodes. NB The pre-patent period of *Dipylidium caninum* is 14-20 days; for *Echinococcus granulosus*, 63-70 days

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

No evidence of clinical toxicity follows either intramuscular or subcutaneous injection at the rate of 100 mg/kg bodyweight administered either to cats or to dogs.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Praziquantel is a pyrazino-isoquinolin derivative, with anthelmintic, specifically cestocidal, 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 and *Echinococcus multilocularis*. Praziquantel is effective against all stages of development of these parasites occurring in the intestines of dogs and cats.

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. 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.

Echinococcus multilocularis does not occur in the UK but is becoming more common in some European countries. As a precautionary measure to prevent the establishment of *E. multilocularis* in the UK, it is recommended that all dogs and cats entering quarantine premises be treated with praziquantel

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Chlorbutol
Propylene glycol

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25ºC.
Do not freeze.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Container material : Type II glass

Container colour : Amber

Closure : Red-brown butyl rubber bung with aluminium overseal.

Container sizes : 10 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bayer plc,
Animal Health Division,
Bayer House,
Strawberry Hill,
Newbury,
Berkshire RG14 1JA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 00010/4098

9. DATE OF FIRST AUTHORISATION

22 June 1994

9.1 Date of Last Renewal of the Authorisation

22 June 2004

10. DATE OF LAST REVISION OF THE TEXT

07 October 2004

PROHIBITION OF SALE, SUPPLY AND/OR USE