SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit 9% Oral Gel for Horses	[AT, DE, PT]
Droncit vet oral gel (for horses)	[DK, FI, IS, NO, SE]
Equitape 90 mg/g Oral Gel for Horses	[IE, UK]
Droncit 9% Gel Oral Cheval	[FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Praziquantel	90.0 mg
Excipients	
Propyl Parahydroxybenzoate (E 216)	0.2 mg
Methyl Parahydroxybenzoate (E 218)	1.4 mg
Excipients ad	1.0 g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Gel
White soft gel

4. CLINICAL PARTICULARS

4.1. Target species

Horse

4.2. Indications for use, specifying the target species

Treatment of infections with cestodes of the species Anoplocephala perfoliata, sensitive to praziquantel.

4.3. Contraindications

None known
Milk: see section 4.11
(Do not use in mares from which milk is taken for human consumption)

4.4. Special warnings for each target species

As tapeworm infestation is unlikely to occur in horses before two months of age, treatment of foals below this age is not considered necessary.
In order to limit excretion of the product and its metabolites on the pasture horses should remain stabled for 2 days after treatment.
Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

MRLs for milk have not been established
See section 4.11 Withdrawal periods

4.5. Special precautions for use

i) Special precautions for use in animals

None.

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

Wash hands thoroughly after treating animals.
Any spillage of the product onto human skin should be removed by washing with soap and water.
Do not eat, drink or smoke during application

4.6. Adverse reactions (frequency and seriousness)

In case of very high infestation levels, destruction of the tapeworms may cause a mild transient colic and loose faeces in the treated horse.

4.7. Use during pregnancy, lactation or lay

The studies conducted in laboratory animals (rat, rabbit) have revealed no evidence of teratogenic, embryotoxic or maternotoxic effects following administration of praziquantel at therapeutic doses. The safety of the veterinary medicinal product following administration to mares during gestation and lactation has not been studied. The product should only be used in mares during pregnancy and lactation after assessment of the benefit/risk balance by the veterinarian.

4.8. Interaction with other medicinal products and other forms of interaction

None known.
In the absence of compatibility studies this veterinary product must not be mixed with other medicinal products.

4.9. Amount to be administered and administration route

Dosage
The recommended dose rate is 1 mg Praziquantel/kg body weight. This corresponds to 6.67 g gel per 600 kg bw.

Administration and duration of treatment
Oral use.
The gel is administered using a measured dose applicator, each graduation of which is marked out to deliver the dose required to treat 50 kg bodyweight

Single treatment only.

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

No adverse effects were reported after the administration of the product for 3 consecutive days up to 5 times the recommended dose.

4.11. Withdrawal periods

Edible tissues: Zero days
Milk: Do not use in mares from which milk is taken for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics
ATCVet Code: QP52AA01

5.1. Pharmacodynamic properties

Praziquantel, a pyrazinoisoquinoline derivative, is used as an anthelmintic in various animal species.
Praziquantel is very rapidly absorbed via the surface of the parasites and evenly distributed in the parasite. Severe damage to the parasite integument occurs very rapidly in vitro and in vivo, resulting in contraction and paralysis of the parasites. The basis for this rapid onset of action is, in particular, the change in Ca++ permeability of the parasite membranes triggered by praziquantel and the resulting disruption of the parasite metabolism.

5.2. Pharmacokinetic particulars

Praziquantel is absorbed very rapidly and almost completely in the stomach and small intestine following oral administration in horses. Maximum serum levels are already reached within the first hour post application. Praziquantel is very rapidly distributed into all organs. The elimination half-live of 14C-praziquantel and its metabolites is 5 hours in horses. Praziquantel is rapidly metabolised in the liver. The main metabolite occurring is the 4-hydroxycyclohexyl derivative of praziquantel. In horses, 24 h after administration, approximately 31 % of the administered dose was eliminated via urine and approximately 24% of the dose was eliminated via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Propyl Parahydroxybenzoate (E 216)
Methyl Parahydroxybenzoate (E 218)
Glycerol
Carbomer
Sodium hydroxide
Purified water

6.2. Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf-life

2 years
Shelf life after first opening the container: discard after first opening.

6.4. Special precautions for storage

No special precautions for storage

6.5. Nature and composition of immediate packaging

6.67 g of 9% gel
High density polyethylene syringe with cap made of high density polyethylene and plastic plunger made of polystyrol with arreting ring.

Presentations to be marketed
Box with one graduated applicator containing 6.67 g gel

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 product or waste material should be disposed of in accordance with the national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm: 00010/4118

9. DATE OF FIRST AUTHORISATION

Date: 31 January 2002

10. DATE OF REVISION OF THE TEXT

Date: May 2014