PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

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. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box with one graduated applicator containing 6.67 g gel

5. TARGET SPECIES

Horses

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
1 mg Praziquantel/kg body weight. This corresponds to 6.67 g gel per 600 kg bw.

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.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

National Bayer subsidiaries respectively

16. MARKETING AUTHORISATION NUMBER(S)

National numbers respectively

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Graduated applicator

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.6 g praziquantel in one graduated applicator

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

One graduated applicator containing 6.67 g gel

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

Edible tissues: Zero days
Milk: read the leaflet before use

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET

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]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
National Bayer subsidiaries

Manufacturer for the batch release:
KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. 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]

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per gram of gel:

Active substance
Praziquantel …….....90.0 mg

Excipients
Propyl Parahydroxybenzoate (E 216) ……0.2 mg
Methyl Parahydroxybenzoate (E 218) ……1.4 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None known
Milk: see Withdrawal period section

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Box with one graduated applicator containing 6.67 g gel for oral use.
The recommended dose rate is 1 mg Praziquantel/kg body weight. This corresponds to 6.67 g gel per 600 kg bw.
A single administration per treatment is effective.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

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.

To the user:

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

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

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