

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bayer Praziquantel 50 mg Tablets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substance**

Praziquantel                    50 mg per tablet

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Tablet.

White tablets.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cats and dogs.

#### **4.2 Indications for use, specifying the target species**

For the treatment of adult tapeworms of cats and dogs. The tablets are effective against both immature and mature forms of adult tapeworms in both cats and dogs.

The product is a highly effective treatment against all the common species of tapeworm infecting cats and dogs in the United Kingdom including *Echinococcus granulosus*, *Taenia ovis*, *Taenia pisiformis*, *Taenia multiceps*, *Taenia hydatigena*, *Taenia taeniaeformis*, and *Dipylidium caninum*. The product 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 kittens and puppies as such animals are rarely infected with tapeworms.

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

#### **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 the establishment of *Echinococcus multilocularis* in the UK, it is recommended that all cats and dogs entering the country be treated with praziquantel.

#### **4.5 Special precautions for use**

##### Special precautions 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 interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

##### *Dosage*

The recommended dose 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        |
|      | 11.0 – 20.0 kg | 2 tablets       |
|      | 21.0 – 30.0 kg | 3 tablets       |
|      | Over 30 kg     | <i>pro rata</i> |
| Cats | Adult          | ½ tablet        |

### *Administration and Duration of Treatment*

For 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 PROPERTIES**

Pharmacotherapeutic group: Pyrazino-isoquinoline derivative, with anthelmintic activity.

ATCvet code: QP52AA01

### **5.1 Pharmacodynamic properties**

The spectrum of action of praziquantel covers all the important species of cestodes in cats and dogs. It specifically includes all *Taenia* species occurring in cats and dogs, *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 cats and dogs.

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 anhydrous  
Maize 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**

Aluminium foil blister or polyethylene coated aluminium blister; silver or white coloured.

Cartons containing 24 (3x8 tablet blisters), 48 (6x8 tablet blisters), 100 (10 x 10 tablet blisters) or 104 tablets (13 x 8 tablet blisters).

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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**

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
NN12 7LS

**8. MARKETING AUTHORISATION NUMBER**

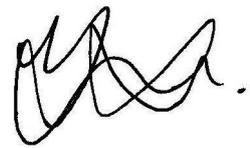
Vm 08007/4153

**9. DATE OF FIRST AUTHORISATION**

25 September 2014

**10. DATE OF REVISION OF THE TEXT**

August 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke ending in a dot.

Approved: 04 August 2022