

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

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

Each gram contains:

Active substance  
Ivermectin 18.7 mg

Excipients  
Titanium Dioxide (E171) 20.0 mg

For the full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Oral paste.  
Clean, white, homogeneous paste

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Horses and donkeys.

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

The product is indicated for the treatment of parasitic infestations in horses and donkeys due to:

##### **Large strongyles**

*Strongylus vulgaris* (adults and arterial larval stages)

*S. edentatus* (adults & tissue larval stages)

*S. equinus* (adults)

*Triodontophorus* spp. (adults)

*Triodontophorus brevicauda*

*Triodontophorus serratus*

*Craterostomum acuticaudatum* (adults)

### **Small Strongyles**

Adult and immature (fourth stage larvae) small strongyles or cyathostomes, including benzimidazole-resistant strains:

*Coronocyclus* spp.

*Coronocyclus coronatus*

*Coronocyclus labiatus*

*Coronocyclus labratus*

*Cyathostomum* spp.

*Cyathostomum catinatum*

*Cyathostomum pateratum*

*Cylicocyclus* spp.

*Cylicocyclus ashworthi*

*Cylicocyclus elongatus*

*Cylicocyclus insigne*

*Cylicocyclus leptostomum*

*Cylicocyclus nassatus*

*Cylicocyclus radiatus*

*Cylicostephanus* spp.

*Cylicostephanus asymmetricus*

*Cylicostephanus bidentatus*

*Cylicostephanus calicatus*

*Cylicostephanus goldi*

*Cylicostephanus longibursatus*

*Cylicostephanus minutus*

*Cylicodontophorus* spp.

*Cylicodontophorus bicornatus*

*Gyalocephalus capitatus*

*Parapoteriostomum* spp.

*Parapoteriostomum euproctus*

*Parapoteriostomum mettami*

*Petrovinema* spp.

*Petrovinema poculatum*

*Poteriostomum* spp.

*Poteriostomum imparidentatum*

### **Lungworms (adult and immatures)**

*Dictyocaulus arnfieldi*

### **Pinworms (adult and immatures)**

*Oxyuris equi*

### **Ascarids (adults and third & fourth stage larvae)**

*Parascaris equorum*

### **Hairworms (adults)**

*Trichostrongylus axei*

**Large-mouth stomach worms (adults)**

*Habronema muscae*

**Neck threadworms (microfilariae)**

*Onchocerca* spp.

**Adult intestinal threadworms:**

*Strongyloides westeri*

**Oral and, gastric stages of bots:**

*Gasterophilus* spp

**4.3 Contra-indications**

The product has been formulated specifically for use in horses and donkeys only. Dogs and cats may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

**4.4 Special warnings for each target species**

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test (s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in a number of countries within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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

##### Special precautions for use in animals:

No special precautions are required.

##### Special precautions to be taken by the person administering the veterinary medicinal product to the animals

Do not smoke, eat or drink while handling the product.

Wash hands after use.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In the case of contact, rinse immediately with plenty of water.

In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package insert or the label to the physician.

#### **4.6 Adverse reactions (frequency and seriousness)**

Some horses carrying heavy infection of *Onchocerca* microfilariae have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

#### **4.7 Use during pregnancy, lactation or lay**

Horses and donkeys of all ages, including pregnant mares and breeding stallions, have been treated with no adverse effect.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

The product has been used in conjunction with other equine health care products and no interactions have been identified.

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

Administer orally to both horses and donkeys at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger

##### Dosing instructions

Unlock the knurled ring by making 1/4 turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight

marking. Turn the knurled ring 1/4 turn to lock in place. Remove the plastic cap from the tip of the nozzle. Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

#### Parasite control program

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations. Foals may be treated initially at 6-8 weeks of age if indicated. Discard any unused material.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

#### **4.11 Withdrawal periods**

Donkeys - meat: 21 days  
Horses - meat: 21 days

Do not use in mares producing milk for human consumption.

### **5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

**ATC Vet Code:** QP54AA01

#### **5.1 Pharmacodynamic properties**

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

## 5.2 Pharmacokinetic properties

### ***Maximum plasma concentration***

In the horse the maximum plasma concentration (average of 32 ng/ml) is reached 6 hours after administration of a dose rate of 0.3 mg ivermectin per kg bodyweight. This peak falls off gradually to an average level of 2 ng/ml at 10 days.

### ***Excretion: length of time and route***

Ivermectin residues (expressed as dihydro B<sub>1a</sub>) in the liver, muscle, kidney, fat and blood were determined with a liquid chromatographic method with fluorescence detection. No residue (except one 28 day fat sample) reached the limit of detection of > 2 ppb 21, 28 and 42 days post dose.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Titanium dioxide (E171)  
Hyprolose  
Hydrogenated Castor Oil  
Propylene Glycol

### 6.2 Major Incompatibilities

None known.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.  
Shelf life after first opening the immediate packaging: use immediately.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Protect from light.

### 6.5 Nature and composition of immediate packaging

The product is available in syringes containing 6.42g, 8,03g or 11.77g of paste.

For syringe intended for the treatment of horses up to 600 kg, containing 6.42g of paste:

White polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with a white polypropylene stop ring.

For syringes intended for the treatment of horses up to 750 kg and 1100 kg, containing 8.03g or 11.77g of paste respectively: White polypropylene syringes barrel with a white rubber cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with a white polypropylene stop ring.

Box of 1 syringe for oral administration of 6.42g

Box of 1 syringe for oral administration of 8.03g

Box of 1 syringe for oral administration of 11.77g

Box of 50 syringes for oral administration of 6.42g

Box of 50 syringes for oral administration of 8.03g

Box of 50 syringes for oral administration of 11.77g

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container. 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**

Boehringer Ingelheim Animal Health UK Ltd  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

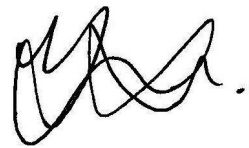
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**9. DATE OF FIRST AUTHORISATION**

18 April 1994

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

August 2022

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

Approved: 15 August 2022