

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Alverin 18.7 mg/g Oral Paste for Horses

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

Active substance:  
Ivermectin: 18.7 mg/g

Excipient(s):  
For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Oral paste.  
A yellow, gel-like paste of uniform consistency.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target Species**

Horses

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

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

##### **Large strongyles**

*Strongylus vulgaris* (adults and arterial larval stages)

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

*S. equinus* (adults)

*Triodontophorus* spp. (adults)

*Triodontophorus brevicauda*

*Triodontophorus serratus*

*Craterostomum acuticaudatum* (adults)

##### **Small Strongyles**

Adults 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* (see section 4.4)

**Hairworms** (adults)

*Trichostrongylus axei*

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

*Habronema muscae*

**Neck threadworms** (microfilariae)

*Onchocerca* spp.

**Intestinal threadworms** (adults)

*Strongyloides westeri*

**Stomach bots** (oral and gastric stages)

Oral and gastric stages of *Gasterophilus* spp.

### 4.3 Contraindications

Not for use in species other than the target species as severe adverse reactions, including fatalities in dogs may occur.

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

### 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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

### 4.5 Special Precautions for Use

#### i. Special precautions for use in animals

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

The product has been formulated specifically for use in horses only. Dogs and cats (especially Collies, Old English Sheep dogs and related breeds or crosses) and also turtles and tortoises 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.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

ii. 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 leaflet or the label to the physician.

iii. Other precautions

Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

#### **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**

Can be used in pregnant mares and in breeding stallions.

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

Ivermectin increases the effects of GABA agonists.

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

Administer orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Each syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under or overdosing

### Dosing instructions

Each weight marking on the syringe plunger will deliver sufficient paste to treat 100 kg bodyweight. 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.

#### **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 1.8mg/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**

Meat and offal 21 days

Do not use in mares producing milk for human consumption.

### **5. PHARMACEUTICAL PROPERTIES**

**Pharmacotherapeutic group: Endectocides –Avermectins - Ivermectin**  
**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 Pharmacokinetics 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 B1a) 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**

Maize Oil  
Polysorbate 80  
Apple Flavour  
Silica Colloidal Anhydrous

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

This is a single use product. The cap should be replaced after use and remaining product should be discarded.

### **6.4 Special Precautions for Storage**

There are no special storage conditions.

### **6.5 Nature and composition of immediate packaging**

Dose graduated disposable polyethylene oral syringe containing 6.42g. The cartons contain one or twenty syringes.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

**7.0 MARKETING AUTHORISATION HOLDER**

Zoetis UK Limited  
5th Floor, 6 St. Andrew Street  
London  
EC4A 3AE

**8. MARKETING AUTHORISATION NUMBER**

Vm 42058/4179

**9. DATE OF FIRST AUTHORISATION**

3 July 2014

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

July 2014

APPROVED T. NASH 3/07/14