

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste, 18.7mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Ivermectin 18.7mg/g

For a 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 of parasitic infestations in horses due to:

Large strongyles

Strongylus vulgaris (adult and arterial larval stages)

S. edentatus (adult and tissue larval stages)

S. equinus (adults)

Triodontophorus spp. (adults)

Triodontophorus brevicauda

Triodontophorus serratus

Craterstomum 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.

Intestinal threadworms (*adults*)

Strongyloides westeri

Stomach bots

Oral and gastric stages of Gastrophilus spp.

4.3 Contraindications

This product has been formulated specifically for use in horses 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 or misadministration of the product.

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 ivermectin (an avermectin) has been reported in *Parascaris equorum* in horses in a number of countries, including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of 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

Where there is significant tissue damage following *Habronema* infestation, additional medical therapies may be required.

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.

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

Do not smoke, drink or eat while handling the product.
Wash hands after use.

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 and lactation

Horses of all ages, including pregnant mares and breeding stallions, have been treated with no adverse effect. For use in lactating mares please see 4.11.

4.8 Interaction with other medicaments and other forms of interaction

None known

4.9 Amounts to be administered and administration routes

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

Dosing Instructions

Each weight marking on the syringe plunger will deliver sufficient paste to treat 100kg bodyweight. Unlock the knurled ring by making $\frac{1}{4}$ 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 $\frac{1}{4}$ turn to lock in place. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the nozzle. 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. Immediately raise the horse's head for a few seconds after dosing.

Parasite control program:

All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings.

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

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 includes 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 period(s)

Meat and offal: 21 days

Animals may not be slaughtered for human consumption during treatment.

Not permitted for use in lactating mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides

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 and 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 and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetics particulars

Following administration of Maximec Horse Oral Paste 18.7mg/g for Horses, ivermectin is rapidly absorbed to reach peak plasma concentration in several hours. This peak falls off gradually over several days.

Ivermectin is eliminated primarily via the faeces. The highest residue levels are found in fat.

At a dose rate of 0.2mg ivermectin per kilogram of bodyweight, plasma levels of ivermectin reach a mean C_{max} concentration of 40.44ng/ml and a mean T_{max} at 8.35 hours. This peak falls off gradually to an average level of 3 ng/ml at 10 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Oil

Polysorbate 80

Colloidal Anhydrous Silica

Apple Flavour (In-house)

6.2 Incompatibilities

No major incompatibility has been identified.
Do not mix with other veterinary medicinal products.

6.3 Shelf-life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Dose graduated disposable polyethylene oral syringe containing 6.42g of a yellow gel-like, apple flavoured, paste of uniform consistency. The syringe is packed into an individual cardboard carton which in turn is packed into an outer display carton containing 24 packed syringes.

6.6 Special Precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.
Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHERISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airtton Close
Tallaght,
Dublin 24.
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4020

9. DATE OF RENEWAL OF THE AUTHORISATION

22 September 2010

10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 19 October 2018

