Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste 18.7 mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Ivermectin Active 18.7 mg/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

Maximec Horse Oral Paste is indicated for the treatment of parasitic infestations in horses due to:

Large strongyles
Strongyles vulgaris (adults and 4th larval [arterial] stages)
S. edentatus (adults and 4th larval [tissue] stages)
S. equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Triodontophorus tenuicollis
Craterstomum acuticaudatum (adults)

Small Stongyles
Adults and immature (fourth stage lumenal 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 asymetricus
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.
Poteriostomum ratzii

Lungworms (adults and immatures)
Dictyocaulus arnfieldi

Pinworms (adults and immatures)
Oxyuris equi

Ascarids (adults and immatures)
Parascaris equorum

Hairworms (adults)
Trichostronglus axei

Large-mouth stomach worms (adults)
Habronema muscae.

Neck Treadworms (microfilariae)
Onchocerca spp.

Intestinal treadworms (adults)
Strongyloides westeri

Stomach bots
Oral and gastric stages of *Gasterophilus* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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 anthelminitics from the same class, over an extended period of time.
- Under dosing, which may be due to underestimation of body weight or mis-administration 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 has been reported in *Parascaris equorum* in horses. 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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelminitic 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

Special precautions for use in animals
Avermectins may not be well tolerated in non-target species. Cases of intolerance, including fatalities, have been reported in dogs, especially collies, Old English Sheepdogs and related breeds or crosses. Maximec Horse Oral Paste has been formulated specifically for use in the horse. Dogs and cats may experience adverse effects 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 or eat while handling the product.
Wash hands after use.
Do not allow cats or dogs to ingest spilled paste or access to used syringes.

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

Maximec Horse Paste can be administered to mares at any stage of pregnancy or lactation. Maximec Horse Paste will not affect the fertility of breeding mares and stallions and can be given to all ages of animals including young foals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

<u>Dosing Instructions</u>
Each weight marking on the syringe plunger will deliver sufficient paste to treat 100 kg bodyweight. Unlock the knurled ring by making ¼ 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 ¼ 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.

<u>Parasite control program</u>
All horses should be included in a regular parasite control program, with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. The product is highly effective against gastro-intestinal, cutaneous and pulmonary nematodes and bots of horses.

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

Mild transitory signs (slowed papillary 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 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)

Animals must not be slaughtered for human consumption during treatment. Horses may be slaughtered for human consumption only 21 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
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 Pharmacokinetic particulars

Following administration of Maximec Paste 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 Cmax concentration of 40.44ng/ml and a mean Tmax at 8.35 hours. This peak falls of gradually to an average level of 3ng/ml at 10 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Apple Flavour
Polysorbate 80
Colloidal Silicon Dioxide
Maize Oil

6.2 Major incompatibilities

No major incompatibilities have been identified.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.
This is a single dose product. Discard after use.

6.4 Special precautions for storage

This veterinary medicine 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 yellowish gel-like, apple-flavoured, paste of uniform consistency.

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

Studies indicate that when Ivermectin comes into contact with the soil it readily and tightly binds to the soil and becomes inactive. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. Do not contaminate lakes or streams as free Ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authoristion: 05 March 2004
Date of last renewal: 04 March 2009

10 DATE OF REVISION OF THE TEXT

May 2019