SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Paste for Horses 18.7 mg/g Oral Paste

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 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

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 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 bodyweight, 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

(i) Special precautions for use in animals

No special precautions are required.

(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 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, The contents of one syringe will treat horses up to 600 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
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.

Parasite control programme

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 and offal: 21 days
Horses - meat and offal: 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-gates 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_{1a}) 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 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25ºC.
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

Vm 08327/4250

9. DATE OF FIRST AUTHORISATION

29 June 2011

10. DATE OF REVISION OF THE TEXT

April 2022

Approved 14 April 2022