SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alomec 18.7 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Ivermectin 18.7 mg/g

Excipient:

Apple Flavour 20 mg/g

For the 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

Alomec 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 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)
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, 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 in animals

No special precautions are required.

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

Do not smoke, drink or eat 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.

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.

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
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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

Parasite control program:
Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control.

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 & offal: 21 days
Not to be used in animals producing milk for human consumption.

5. PHARMACOLOGICAL 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 Pharmacokinetics particulars

Following administration of Alomec 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

Apple Flavour
Polysorbate 80
Colloidal Anhydrous Silica
Maize Oil Refined

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Protect from light.
Once opened, use immediately.

6.5 Nature and composition of immediate packaging

Carton containing one dose graduated disposable polyethylene oral syringe containing 6.42g of a yellow gel-like, apple flavoured, paste of uniform consistency.
Carton containing 24 individually packed syringes
Not all pack sizes may be marketed

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

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4034

9. DATE OF FIRST AUTHORISATION

02 December 2009

10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 26 October 2018