

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

Each g contains:

Active substance:

Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Apple Flavour	20 mg
Polysorbate 80	
Colloidal Anhydrous Silica	
Maize Oil Refined	

A yellow, gel-like paste of uniform consistency.

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

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)
Gastrophilus spp.

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

No special precautions are required.

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. This veterinary medicinal product may cause skin and eye irritation. Therefore, the user should avoid contact of the veterinary medicinal 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.

Special precautions for the protection of the environment:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

3.6 Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data)	Oedema ¹ , Pruritus ¹
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¹Experienced by some horses carrying heavy infection of *Onchocerca* microfilariae 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Horses of all ages, including pregnant mares and breeding stallions, have been treated with no adverse effect.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

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 $\frac{1}{4}$ 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:

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat & offal: 21 days

Not to be used in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Protect from light.

5.4 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.

Pack sizes:

Carton box containing 1 × 6.42 g syringe.
Carton box containing 24 × 6.42 g syringes.

Not all pack sizes may be marketed

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/4034

8. DATE OF FIRST AUTHORISATION

02 December 2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 29 September 2026