IVERMECTIN

Alomec®

18.7 mg/g

Oral Paste for Horses

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MARKETING AUTHORISATION HOLDER AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

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STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

The product is a ready-to-administer, 18.7 mg/g oral paste formulation of ivermectin with apple flavour.

INDICATION

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 elongates; Cylicocyclus insigne; Cylicocyclus leptostomum; Cylicocyclus nassatus; Cylicocyclus radiates. 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.

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.

ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Horses

DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 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.

ADVICE ON CORRECT ADMINISTRATION

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.

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

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

WITHDRAWAL PERIOD

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

SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Protect from light.
Once opened, use immediately.

SPECIAL WARNINGS FOR EACH TARGET SPECIES

None

USER WARNINGS

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.

USE DURING PREGNANCY AND LACTATION

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

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

None known

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.

MAJOR INCOMPATIBILITIES

No major incompatibilities have been identified.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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.

DATE ON WHICH THE PACKAGE LEAFLET APPROVED

09.09.2014

OTHER INFORMATION

DERIVED FROM NATURALLY OCCURRING SUBSTANCES

Ivermectin, the active ingredient of Alomec® is produced from a naturally occurring fungus (Streptomyces avermitilis). Alomec® has a wide safety margin. At the recommended rate Alomec® can be used with complete confidence in foals, mares, ponies and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been treated has not been affected.

POM-VPS

Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person
To be supplied only on veterinary prescription.
For Animal Treatment Only.

Vm 12597/4050

AKKER®