IVERMECTIN- ivermectin paste Med-Pharmex, Inc

Ivermectin Paste

Approved by FDA under ANADA # 200-390

Anthelmintic and Boticide

For Oral Use in Horses Only

Contents will treat up to 1250 lb body weight.

Removes worms and bots with a single dose.

Each Syringe Contains 0.21oz (6.08 g) Apple Flavor Ivermectin Paste

For Oral Use in Horses Only

Contents will treat up to 1500 lb body weight.

Removes worms and bots with a single dose.

Each Syringe Contains 0.26oz (7.30 g) Apple Flavor Ivermectin Paste

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Ivermectin Paste provides effective treatment and control of the following parasites in horses.

Large Strongyles (adults) - *Strongylus vulgaris* (also early forms in blood vessels), *S*. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds) - Coronocyclus spp. including C. coronatus, C. labiatus and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylicocyclus spp. including C. insigne, C. leptostomum, C. nassatus and C. brevicapsulatus, Cylicodontophorus spp., Cylicostephanus spp. including C. calicatus, C. goldi, C. longibursatus and C. minutus, and Petrovinema poculatum; Small Strongyles - Fourth-stage larvae; Pinworms (adults and fourth-stage larvae) -Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae) - Parascaris equorum; Hairworms (adults) - Trichostrongylus axei; Large-mouth Stomach Worms (adults) - Habronema muscae; Bots (oral and gastric stages) - Gasterophilus spp. including G. intestinalis and G. nasalis; **Lungworms** (adults and fourth-stage larvae) - Dictyocaulus arnfieldi; Intestinal Threadworms (adults) - Strongyloides westeri; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

DOSAGE:

Ivermectin Paste Net Wt: 0.21 oz (6.08 g)

This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION:

(1) While holding plunger, turn the knurled ring on the plunger to the right to move it up towards the barrel until the side nearest the barrel aligns with the line at the prescribed weight marking, as shown in the pictogram.



(2) Ensure the ring is secured at the appropriate weight by turning the ring 1/4 turn to the left.

- (3) Make sure that the horse's mouth contains no feed.
- (4) Remove the cover from the tip of the syringe.
- (5) Insert the syringe tip into the horse's mouth at the space between the teeth.
- (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue.
- (7) Immediately raise the horse's head for a few seconds after dosing.

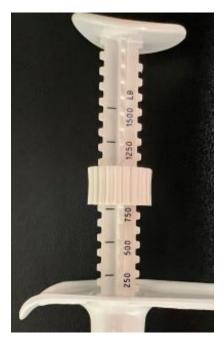
Ivermectin Paste 1.87% Net Wt: 0.26 oz (7.30 g)

This syringe contains sufficient paste to treat one 1500 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION:

(1) While holding plunger, turn the knurled ring on the plunger to the right to moveit up towards the barrel until the side nearest the barrel aligns with the line at the prescribed weight marking, as shown in the pictogram.



- (2) Make sure that the horse's mouth contains no feed.
- (3) Remove the cover from the tip of the syringe.
- (4) Insert the syringe tip into the horse's mouth at the space between the teeth.
- (5) Depress the plunger as far as it will go, depositing paste on the back of the tongue.
- (6) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: 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. Consult your veterinarian for a control program to meet your specific needs. Ivermectin Paste 1.87% effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES: **Broad-spectrum Control**– Ivermectin Paste 1.87% kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. Ivermectin Paste 1.87% is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: Ivermectin Paste 1.87% may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

WARNING: Do not use in horses intended for human consumption.

Not for use in humans. Keep this and all drugs out of reach of children.

Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a SDS, contact Med-Pharmex at (800) 587-4306.

PRECAUTIONS: Ivermectin Paste 1.87% has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

OTHER WARNINGS: Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Environmental Safety: Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS: Swelling and itching reactions after treatment with Ivermectin Paste 1.87% have occurred in horses carrying heavy infections of neck threadworm microfilariae (*Onchocerca* sp.) . These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with Ivermectin Paste 1.87%. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

CONTACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Med-Pharmex at (800) 587-4306 or complaints@medpharmex.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

STORAGE INFORMATION: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

Manufactured by:

Med-Pharmex, Inc. Pomona, CA 91767

Rev. 09/2023





IVERMECTIN

ivermectin paste

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:54925-048

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	1.87 g in 100 g

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:54925-048-06	6.08 g in 1 SYRINGE				
2	NDC:54925-048-07	7.30 g in 1 SYRINGE				

Marketing I	arketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANADA	ANADA200390	09/27/2012				

Labeler - Med-Pharmex, Inc (025353699)

Revised: 9/2023 Med-Pharmex, Inc