DURAMECTIN- ivermectin paste
Durvet, Inc.

DuraMectin (ivermectin) Paste

FDA Approved under ANADA # 200-390

DuraMectin (ivermectin) Paste 1.87% - Anthelmintic and Boticide
Removes worms and bots with a single dose.

Each Syringe Contains 0.21 oz (6.08 g) IVERMECTIN PASTE Net Wt: 0.21 oz (6.08 g) Contents will treat up to 1250 lb body weight.

For Oral Use in Horses Only

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 AND ADMINISTRATION:

DuraMectin (ivermectin) Paste 1.87% 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.

(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (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.

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 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 kills important internal parasites, including bots and the arterial stages of S. vulgaris, with a single dose. Ivermectin Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: Ivermectin Paste 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.

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.

To report adverse reactions in users, to obtain more information, or to obtain a SDS, contact Durvet, Inc. at 800-821-5570.

PRECAUTIONS: Ivermectin Paste 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.

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 DuraMectin (ivermectin) Paste 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 DuraMectin (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

STORAGE:

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).

Rev.: 12-2022

PACKAGE LABEL:

DURAMECTIN

ivermectin paste

Product Information			
Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:30798-970
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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	2.0 g in 100 g
TROLAMINE (UNII: 9O3K93S3TK)	0.47 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	1.7 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	93.96 g in 100 g

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	APPLE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30798-970-81	6.08 g in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200390	10/01/2022	

Labeler - Durvet, Inc. (056387798)

Registrant - Med-Pharmex, Inc. (025353699)

Establishment

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc.		025353699	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Qilu King-Phar Pharmaceutical Co. Ltd.		421524323	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Hisun Pharmaceutical Co.		654211754	api manufacture