

DURAMECTIN- ivermectin paste
Durvet, Inc.

DuraMectin (ivermectin) Paste

DuraMectin Paste 1.87%

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 0.21 oz (6.08 g) IVERMECTIN PASTE

Net Wt: 0.21 oz (6.08 g)

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) – *Coronocylus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* 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:

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.

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. DURAMECTIN 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- DURAMECTIN Paste 1.87% kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. DURAMECTIN Paste 1.87% is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: DURAMECTIN 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 Durvet, Inc. at (800) 821-5570.

PRECAUTIONS: DURAMECTIN 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 DURAMECTIN Paste 1.87% have occurred in horses carrying heavy infections of neck threadworm microfilariae (*Onchocerca* sp.) microfilariae. 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 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 Durvet, Inc. at (800) 821-5570 or info@durvet.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 for:

Durvet, Inc.
Blue Springs, MO 64014, U.S.A.

rev 11/2023

NDC 30798-970-81

DURAMECTIN
(ivermectin) **PASTE 1.87%**

durvet
www.durvet.com

**Anthelmintic and Boticide
For Oral Use in Horses Only**

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms, Bots. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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 or eating when handling. Wash hands after use. Avoid contact with eyes.

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).

Approved by FDA under ANADA # 200-390

NET WT 0.21 oz (6.08 g)

Lot No./Exp. Date:
Rev. 11/2023

REV 11/20

Lot # / Exp. Date



DURAMECTIN
Anthelmintic & Boticide

DURAMECTIN
(ivermectin) PASTE 1.87%

For Oral Use In Horses Only

Removes worms and bots with a single dose

Net Wt. 0.21 oz (6.08 g)
1250 lb body weight
Approved by FDA under
ANADA # 200-390

Manufactured by Durvet, Inc.
11 Springs, MD 20714, U.S.A.
www.durvet.com

285108 R01

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 an SDS, contact Durvet, Inc. at (800) 921-6570.

PRECAUTIONS: DURAMECTIN 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 excipient 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.

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasites. DURAMECTIN Paste 1.87% provides effective treatment and control of the following parasites in horses.

Large Strongyles (adults) – *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (late tissue stages), *S. edentatus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus* and *Oxyostomum aciculicaudatum*.

Small Strongyles (adults), including those resistant to some benzimidazole class compounds – *Coronaria* spp. including *C. coronatus*, *C. labialis* and *C. labialis*, *Oxyostomum* spp. including *O. columbianum* and *O. perianthum*, *Cylicocyclus* spp. including *C. magnum*, *C. leptomastum*, *C. minutus* and *C. brevicapitatus*, *Cylicodontophorus* spp. including *C. calcaratus*, *C. goldi*, *C. langibursatus* and *C. minutus*, and *Filicostium pascuatum*.

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)** – *Gastrophilus* spp. including *G. intestinalis* and *G. nasalis*; **Longworms (adults and fourth-stage larvae)** – *Cylicostephanus ardeoli*; **Intestinal Threadworms (adults)** – *Strongylus westeri*; **Summer Sores** caused by *Habronema* and *Draconcha* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSEAGE: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 51 mcg ivermectin per lb (230 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.

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. DURAMECTIN Paste 1.87% effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arthropods caused by *Strongylus vulgaris*.

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

ANIMAL SAFETY: DURAMECTIN 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.

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

ADMINISTRATION:

- 1) While holding plunger, turn the knurled ring on the plunger to the right to move it up towards the barrel until the scale nearest the barrel aligns with the line at the appropriate weight marking as shown in the picturegram.
- 2) Ensure the ring is secured at the appropriate weight by turning the ring ¼ 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.

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: 15FX9V2JP)			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

Revised: 12/2024

Durvet, Inc.