

EQUIMAX- ivermectin and praziquantel paste
Bimeda, Inc.

Equimax®
(ivermectin 1.87% / praziquantel 14.03%)
Oral Paste
Anthelmintic and Boticide

FOR ORAL USE IN HORSES ONLY

For the treatment and control of worms and bots in horses with a single dose.

Safe for horses **4 weeks of age and older**. Contents will treat up to 1320 lb body weight.

Net Weight: 0.225 oz (6.42 g)

INDICATIONS

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. EQUIMAX (ivermectin/praziquantel) Oral Paste is indicated for the treatment and control of the following parasites:

Tapeworms

Anoplocephala perfoliata

Large Strongyles (adults)

Strongylus vulgaris (also early forms in blood vessels)

S. edentatus (also tissue stages)

S. equinus

Triodontophorus spp.

Small Strongyles (adults, including those resistant to some benzimidazole class compounds)

Cyathostomum spp.

Cylicocycclus spp.

Cylicostephanus spp.

Cylicodontophorus spp.

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.

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

This syringe contains sufficient paste to treat one 1320-lb horse at the recommended dose rate of 91

mcg ivermectin per lb (200 mcg/kg) and 0.68 mg praziquantel per lb (1.5 mg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 220 lb (100 kg) of body weight.

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.

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 4 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. EQUIMAX Oral Paste effectively controls gastrointestinal nematodes, cestodes and bots of horses. Regular treatment will reduce the chances of colic caused by *Anoplocephala perfoliata* and verminous arteritis caused by *Strongylus vulgaris*.

Product Advantages: Broad-spectrum Control: EQUIMAX Oral Paste kills important internal parasites, including tapeworms, bots and the arterial stages of *S. vulgaris*, with a single dose. EQUIMAX Oral Paste contains two potent antiparasitic agents that are neither benzimidazoles nor organophosphates.

SAFETY

EQUIMAX Oral Paste may be used in horses 4 weeks of age and older. Stallions and breeding, pregnant or lactating mares may be treated without adverse effects on fertility.

In a tolerance study in which 3- to 4-week-old foals were treated at 10X once, loose watery stools were observed on post-treatment days 1, 2, and 5-9 in one foal. These signs resolved without treatment by day 10, and no other foals were affected.

In a reproductive safety study, eleven mares were treated with a 3X dose of EQUIMAX Oral Paste every two weeks throughout breeding, pregnancy and lactation, up until the foal was three months of age. Ten mares served as controls and were treated with the vehicle paste in a similar manner. An increased incidence of colic was observed in treated mares as compared to control mares. In addition, elevations of GGT and AST were more frequent in the 3X treated mares, and in two mares these enzymes were elevated at the time of colic episodes.

One treated mare was dropped from the study because she did not conceive after three breeding attempts.

Two treated mares had abnormally short diestrous periods of two days and eight days on the first

estrous cycle following the birth of the study foal. In addition, one of these two mares failed to ovulate in the second and third estrous cycles.

In the first few weeks of life, foals born to the 3X treated mares had a higher incidence of transient ocular discharge and gastrointestinal disturbances (loose stools, diarrhea) and depression requiring medical intervention as compared to foals born to control mares.

PRECAUTIONS

EQUIMAX Oral Paste has been formulated specifically for use in horses and ponies **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

WARNING

Do not use in horses intended for human consumption.

HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Refrain from eating or smoking 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 Bimeda Inc. at 1-888-524-6332.

ENVIRONMENTAL WARNINGS

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.

POST APPROVAL EXPERIENCE

(Rev. 2010): The following adverse events are based on post-approval adverse drug experience reporting with Equimax. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events are listed in decreasing order of reporting frequency: Abdominal pain, diarrhea, depression/lethargy and anorexia.

To report side effects, call Bimeda Inc. at 1-888-524-6332. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

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 geographical 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.

STORAGE

Store at room temperature (25°C/77°F), with excursions permitted between 15°–30°C (59°–86°F).

NOTE TO USER

Swelling and itching reactions after treatment with ivermectin paste have occurred in horses carrying heavy infections of neck threadworm (*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 EQUIMAX Oral Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

To report adverse reactions, call Bimeda Inc. at 1-888-524-6332.

Approved by FDA under NADA # 141-215

Manufactured by:

Virbac AH Inc.
P.O. Box 162059
Fort Worth, TX 76161

Made in USA

Equimax is a Registered Trademark of Virbac SA.
301985-03
Rev 02/20

Distributed by:

Bimeda, Inc.
Le Sueur, MN 56058

EQUIMAX carton



EQUIMAX syringe

EQUIMAX[®]
(ivermectin 1.87%
praziquantel 14.03%)
Oral Paste

Anthelmintic and Boticide
 FOR ORAL USE IN HORSES ONLY

Net Weight: 0.225 oz (6.42 g)

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Equimax is indicated for the treatment and control of the following parasites: Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms, Tapeworms, Lungworms and Bots. See package insert for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Manufactured by: Virbac AH Inc.
 P.O. Box 162059
 Fort Worth, Texas 76161

Lot:

Exp:

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Made in USA



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 Le Sueur, MN 56058

Rev 02/20
 301984-03

EQUIMAX

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Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:6 1133-7000
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	200 ug
praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	praziquantel	1.5 mg

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 1133-7000-1	1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141215	01/14/2010	

Labeler - Bimeda, Inc. (060492923)

Revised: 8/2020

Bimeda, Inc.