

INTERVET INC., MERCK ANIMAL HEALTH

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Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the USA product label or package insert.

SAFE-GUARD® EQUINE DEWORMER (25 G)

Intervet/Schering-Plough Animal Health

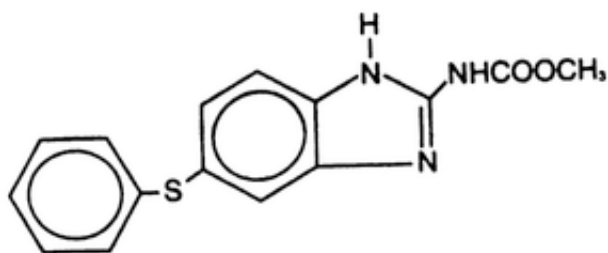
(fenbendazole)

Paste 10% (100 mg/g)

For use in animals only.

DESCRIPTION:

Safe-Guard® (fenbendazole) Paste 10% contains the active anthelmintic, fenbendazole. The chemical name of fenbendazole is methyl 5-(phenylthio)-2-benzimidazole carbamate. The chemical structure is:



Each gram of Safe-Guard® (fenbendazole) Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

ACTIONS:

The antiparasitic action of Safe-Guard® (fenbendazole) Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

INDICATIONS:

Safe-Guard® (fenbendazole) Paste 10% is indicated for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and arteritis caused by fourth stage larvae of *Strongylus vulgaris* in horses.

Safe-Guard® (fenbendazole) Paste 10% is approved for use concomitantly with an approved form of trichlorfon. Trichlorfon is approved for the treatment of stomach bots (*Gasterophilus* spp.) in horses. Refer to the manufacturer's label for directions for use and cautions for trichlorfon.

CONTRAINDICATIONS:

There are no known contraindications for the use of Safe-Guard® (fenbendazole) Paste 10% in horses.

PRECAUTIONS:

Side effects associated with Safe-Guard® (fenbendazole) Paste 10% could not be established in well-controlled safety studies in horses with single doses as high as 454 mg/lb (1,000 mg/kg) and 15 consecutive daily doses of 22.7 mg/lb (50 mg/kg). Particularly with higher doses, the lethal action of fenbendazole may cause the release of antigens by the dying parasites. This phenomenon may result in either a local or systemic hypersensitive reaction. As with any drug, these reactions should be treated symptomatically.

Safe-Guard® (fenbendazole) Paste 10% has been evaluated for safety in pregnant mares during all stages of gestation with doses as high as 11.4 mg/lb (25 mg/kg) and in stallions with doses as high as 11.4 mg/lb (25 mg/kg). No adverse effects on reproductivity were detected. The recommended dose for control of 4th stage larvae of *Strongylus vulgaris*, 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares.

Internal Parasites: Regular deworming at intervals of six to eight weeks may be required due to the possibility of reinfection.

Migrating Tissue Parasites: In the case of 4th stage larvae of *Strongylus vulgaris*, treatment and retreatment should be based on the life cycle and the epidemiology. Treatment should be initiated in the spring and repeated in the fall after a six month interval.

Optimum Deworming Program for control of *S. vulgaris*: Optimum reduction of *S. vulgaris* infections is achieved by reducing the infectivity of the pastures. When horses are running on pasture, in temperate North America, maximum pasture infectivity occurs in October-December. If horses are removed from those pastures in January, pasture infectivity will decline to zero by July 1. Egg production of *S. vulgaris* is minimal from January through April, peaking in August and declining to minimal values in December.

Recommended Deworming Program: **December 1, February 1, **April 1**, June 1, August 1, **October 1**.

The two treatments that are in bold type are the recommended periods when the 5-day treatment regimen for the control of the migrating larvae of *S. vulgaris* should be performed.

**For other areas in the world, retreatment periods for the migrating larvae of *S. vulgaris* may be different; consult with your veterinarian.

CAUTIONS: Keep this and all medication out of the reach of children.

When using Safe-Guard® (fenbendazole) Paste 10% concomitantly with trichlorfon, refer to the manufacturer's labels for use and cautions for trichlorfon.

WARNING: Do not use in horses intended for food.

DOSAGE:

Safe-Guard® (fenbendazole) Paste 10% is administered orally at a rate of 2.3 mg/lb (5 mg/kg) for the control of large strongyles, small strongyles, and pinworms. One syringe will deworm a 1,100 lb horse. For foals and weanlings (less than 18 months of age) where ascarids are a common problem, the recommended dose is 4.6 mg/lb (10 mg/kg); one syringe will deworm a 550 lb horse.

For control of encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, and fourth stage larvae of *Strongylus vulgaris*, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 550 lbs body weight per day.

SEE PRECAUTIONS FOR RETREATMENT RECOMMENDATIONS.

DIRECTIONS FOR USE:

1. Determine the weight of the horse.
2. Remove syringe tip.
3. Turn the dial ring until the edge of the ring nearest the tip lines up with zero.
4. Depress plunger to advance paste to tip.
5. Now set the dial ring at the graduation nearest the weight of the horse (do not underdose).
6. Horse's mouth must be free of food.
7. Insert nozzle of syringe through the interdental space and deposit the paste on the back of the tongue by depressing the plunger.

HOW SUPPLIED:

Safe-Guard® (fenbendazole) Paste 10% Equine Dewormer is supplied in 25 g syringes.

Power-Dose™ Parasite Critical Care Kit Includes: 10x25 g tubes, rotational deworming barn chart, complete guide to encysted small strongyles, rotational deworming manual.

Store at or below 25°C (77°F).

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT AND CONTROL OF PARASITISM.

Manufactured by: DPT Laboratories, San Antonio, TX 78215

Distributed by: **Intervet Inc.**, Millsboro, DE 19966

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