

**SAFE-GUARD- fenbendazole paste**  
**Merck Sharp & Dohme Corp.**

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**safe-guard®**  
**(fenbendazole)**

Paste 10% (100 mg/g)

**HORSE AND CATTLE DEWORMER**

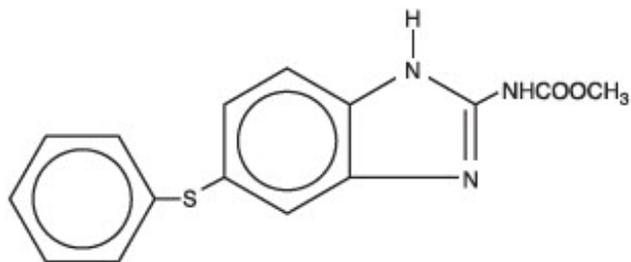
797851 R1

**DESCRIPTION:**

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

The CAS Registry Number is 43210-67-9.

The chemical structure is:



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

**ACTIONS:**

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

**INDICATIONS:**

**Horses:** For the treatment and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and for the control of arteritis caused by 4th stage larvae of *Strongylus vulgaris* in horses.

**Beef and Dairy Cattle:** For the treatment and control of: Lungworms: Adult *Dictyocaulus viviparus*; Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), Adult and fourth stage larvae barberpole worms (*Haemonchus contortus*), fourth stage larvae barberpole worms (*H. placei*), and Adult and fourth stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (Adult and fourth stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms

(*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* & *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

One syringe deworms 4 (1,000 lb) cattle or 4 (1,000 lb) horses at a dose of 5 mg/kg or 4 (500 lb) horses at a dose of 10 mg/kg to treat ascarid infections.

## **PRECAUTIONS:**

**Horses:** Side effects associated with Safe-Guard® 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). At higher dose levels, 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 hypersensitivity reaction varying in severity from itching or a rash to increased respiration and collapse. A veterinarian should be consulted if this type of reaction is suspected.

Safe-Guard® 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 reproduction were detected. The recommended dose for control of 4th stage *Strongylus vulgaris* larvae, 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares.

## **DOSAGE:**

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.

**Horses:** Safe-Guard® 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. Each mark on the plunger rod corresponds to a dose of 2.3 mg/lb (5 mg/kg) for 250 lb body weight.

For foals and weanlings (less than 18 months of age) where ascarids are a common problem, the recommended dose of 4.6 mg/lb (10 mg/kg), or two marks, will deworm a 250 lb horse.

For control of hypobiotic (encysted early 3rd stage), late 3rd stage, and 4th stage cyathostome larvae, as well as 4th stage *Strongylus vulgaris* larvae, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer two marks for each 250 lb body weight per day.

**Beef and Dairy Cattle:** Safe-Guard® Paste 10% is administered orally at a rate of 2.3 mg/lb (5 mg/kg) or 11.5 g Safe-Guard® Paste for 500 lb body weight (227 kg).

**Withdrawal Periods and Residue Warnings:** Milk taken during treatment and for 96 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

**WARNINGS:** NOT FOR USE IN HUMANS. KEEP OUT OF REACH OF CHILDREN. The Safety Data Sheet (SDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-800-211-3573. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS, or <http://www.fda.gov/reportanimalae>.

**OTHER WARNINGS:** Do not use in horses intended for human consumption.

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.

**DIRECTIONS FOR USE:**

1. Determine the weight of the animal.
2. Remove syringe tip.
3. Turn the dial ring until the edge of the ring nearest the tip lines up with zero.
4. Fully depress plunger and discard expelled paste. Syringe is ready for dosing.
5. Each mark on the plunger rod corresponds to a dose of 2.3 mg/lb (5 mg/kg) for 250 lb body weight, or a dose of 4.6 mg/lb (10 mg/kg) for 125 lb body weight (the 10 mg/kg dose is for horses only).

Dial the ring edge nearest the tip back by the calculated number of marks on the plunger rod corresponding to the animal's body weight.

Examples:

<b>Body Weight</b>	<b>Number of marks for 2.3 mg/lb (5 mg/kg) dose for cattle or horses</b>	<b>Number of marks for 4.6 mg/lb (10 mg/kg) dose for horses only</b>
250 lb	1	2
500 lb	2	4
750 lb	3	6
1000 lb	4	8
1500 lb	6	12

6. The animal's mouth should be free of food. Insert nozzle of syringe through the interdental space and deposit the paste on the back of the tongue by depressing the plunger.
7. Repeat steps 1, 5 and 6 for each additional animal.

**HOW SUPPLIED:**

Safe-Guard<sup>®</sup> Paste 10% Horse and Cattle Dewormer is supplied in 92 gram syringes.

Store at or below 25°C (77°F).

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

Formulated in France.

Distributed by:

Intervet Inc. (d/b/a Merck Animal Health)

Rahway, NJ 07065

Approved by FDA under NADA # 132-872

Approved by FDA under NADA # 120-648

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Rev. 08/23

MERCK

Animal Health

**PRINCIPAL DISPLAY PANEL - 25 g Syringe Carton**

MERCK

Animal Health

safe-guard<sup>®</sup>  
(fenbendazole)

Equine  
Dewormer

25 gram Paste 10%  
(100 mg/g)

MERCK

Animal Health

# safe-guard<sup>®</sup>

(fenbendazole)



# safe-guard<sup>®</sup>

(fenbendazole)



## Equine Dewormer

25 gram Paste 10%  
(100 mg/g)



**INDICATIONS:**  
For the control of hypobiotic (encysted early 3rd stage), late 3rd stage, and 4th stage cyathostome larvae, the recommended dose is 4.6 mg/kg (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 550 lb body weight per day. Instructions: Ensure each animal receives a complete dose based on a current body weight. Linear dosing may result in ineffective treatment, and encourage the development of parasite resistance.

**DIRECTIONS FOR USE:**  
1. Determine the weight of the horse.  
2. Remove syringe tip.  
3. Turn the dial ring until the edge of the dialing inner scale lines up with the weight of the horse in pounds.  
4. Draw paste into syringe.  
5. Set the dialing at the gestation for the dosage rate of 0.5 mg/kg. For the dosage rate of 1.0 mg/kg, set the dialing at two times (double) the horse's weight.  
6. Horse's mouth should 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.

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

**HOW SUPPLIED:**  
Safe-guard<sup>®</sup> Paste 10% Equine Dewormer is supplied in 25 gram syringes.

Store at or below 25°C (77°F). Use Only as Directed

Renbendazole (active ingredient) made in: see imprint. Formulated in France.

Distributed by: Intervet Inc. (d/b/a Merck Animal Health), NJ 07065

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Rev. 07/23



## safe-guard<sup>®</sup>

(fenbendazole)

Paste 10% (100 mg/g) Equine Dewormer

**DESCRIPTION:**  
Safe-guard<sup>®</sup> (fenbendazole) Paste 10% contains the active ingredient, fenbendazole. The chemical name of fenbendazole is methyl 5-(phenylthio)-2-thiazolonecarboxylate.  
The chemical structure is:



Each gram of Safe-guard<sup>®</sup> Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

**ACTIONS:**  
The antiparasitic action of Safe-guard<sup>®</sup> Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

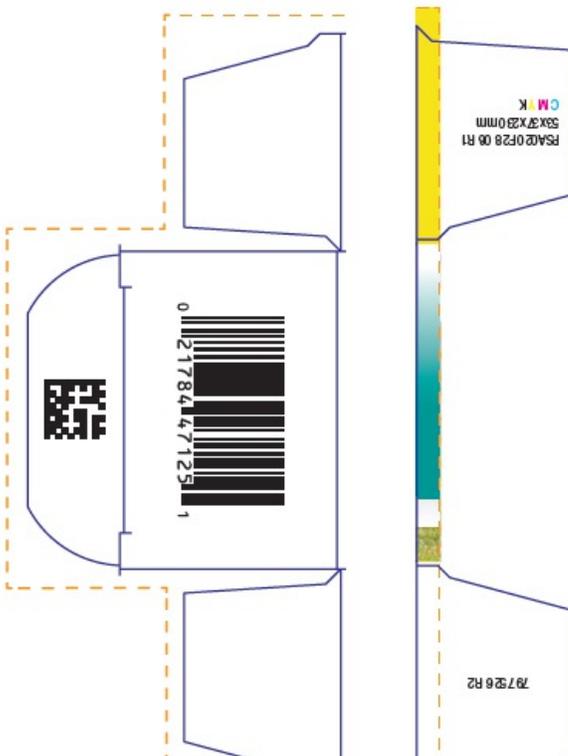
**INDICATIONS:**  
Safe-guard<sup>®</sup> Paste 10% is indicated for the treatment and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and for the control of arthritis caused by 4th stage larvae of *Strongylus vulgaris* in horses.

**PRECAUTIONS:**  
Side effects associated with Safe-guard<sup>®</sup> Paste 10% occur only at the established level-controlled safety studies in horses with single doses as high as 4.6 mg/kg (10.0 mg/kg) and 15 consecutive daily doses of 2.2 mg/kg (5.0 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 hypersensitivity reaction. As with any drug, these reactions should be treated symptomatically. Safe-guard<sup>®</sup> Paste 10% has been evaluated for safety in pregnant mares during all stages of gestation with doses as high as 11.4 mg/kg (25 mg/kg) and its stallions with doses as high as 11.4 mg/kg (25 mg/kg). No adverse effects on reproduction were detected. The recommended doses for control of 4th stage *Strongylus vulgaris* larvae, 4.6 mg/kg (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares.

**WARNING: NOT FOR USE IN HUMANS. KEEP OUT OF REACH OF CHILDREN.** The Safety Data Sheet (SDS) contains more detailed occupational safety information. For customer service, adverse effect reporting, and/or a copy of the SDS, call 1-800-211-3573. For additional information about adverse drug experiences reporting for animal drugs, contact FDA at 1-866-FDAVETS, or <http://www.fda.gov/ahr/ahrt.html>.

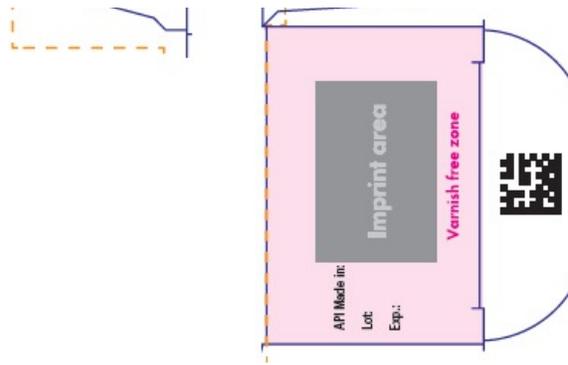
**OTHER WARNINGS:** Do not use in horses intended for human consumption.

Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with dewormer used in conjunction with parasite management practices is appropriate to the geographic area and the intended use of the dewormer. For development of parasite resistance, avoid concurrent use of other dewormers, baits, and parasite management other than deworming. For deworming 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.



PSA 0128 08 R1  
53X37X23 0mm  
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79726 R2



## **PRINCIPAL DISPLAY PANEL - 92 g Syringe Carton**

safe-guard®  
(fenbendazole)

Dewormer

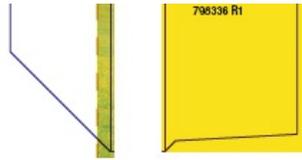
for Beef & Dairy Cattle and Horses  
92 g Paste 10% (100 mg/g)

One syringe deworms 4 (1,000 lb) cattle or 4 (1,000 lb) horses at a dose of 5 mg/kg or 4 (500 lb) horses at a dose of 10 mg/kg to treat ascarid infections.

Net Weight 92 g (3.2 oz)

MERCK  
Animal Health





## **PRINCIPAL DISPLAY PANEL - 290 g Syringe Carton**

safe-guard®  
(fenbendazole)

Dewormer

for Beef & Dairy Cattle  
290 g Paste 10% (100 mg/g)

One tube deworms 12 (1,000 lb) cattle  
or 58 animals of 220 lb each.

To be used only with Safe-Guard® dosing equipment.

Net Weight 290 g (10.2 oz)

MERCK  
Animal Health



<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:57926-083
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FENBENDAZOLE</b> (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)	FENBENDAZOLE	100 mg in 1 g

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	APPLE, CINNAMON	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-083-44	1 in 1 CARTON		
1		25 g in 1 SYRINGE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA120648	06/19/1981	

## SAFE-GUARD

fenbendazole paste

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:57926-084
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FENBENDAZOLE</b> (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)	FENBENDAZOLE	100 mg in 1 g

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	APPLE, CINNAMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-084-46	1 in 1 CARTON		
1		92 g in 1 SYRINGE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA120648	06/19/1981	

## SAFE-GUARD

fenbendazole paste

### Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-085
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FENBENDAZOLE (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)	FENBENDAZOLE	100 mg in 1 g

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE, CINNAMON	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-085-47	1 in 1 CARTON		
1		290 g in 1 SYRINGE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA132872	03/07/1984	

Revised: 11/2024

Merck Sharp & Dohme Corp.