

SAFE-GUARD- fenbendazole paste
Merck Sharp & Dohme

safe-guard®
(fenbendazole)

Paste 10% (100 mg/g)

HORSE AND CATTLE DEWORMER

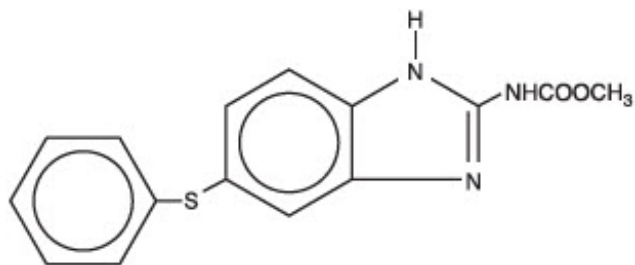
396663 R13

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:

Body Weight	Number of marks for 2.3 mg/lb (5 mg/kg) dose for cattle or horses	Number of marks for 4.6 mg/lb (10 mg/kg) dose for horses only
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[®] 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.

Fenbendazole (active ingred.) made in China. Formulated in France.

Distributed by:

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

Madison, NJ 07940

Approved by FDA under NADA # 132-872

Approved by FDA under NADA # 120-648

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Rev. 09/20

MERCK

Animal Health

PRINCIPAL DISPLAY PANEL - 25 g Syringe Carton

MERCK

Animal Health

safe-guard[®]
(fenbendazole)

Equine
Dewormer

25 gram Paste 10%
(100 mg/g)

MERCK

Animal Health

safe-guard[®]

(fenbendazole)



safe-guard[®]

(fenbendazole)



Equine
Dewormer
25 gram Paste 10%
(100 mg/g)



DOSAGE:
For foals and yearlings (less than 18 months of age) where ascariids are a common problem, the recommended dose is 4.5 mg/lb (10 mg/kg); one syringe will deworm a 550 lb horse. For the control of large strongyles, small strongyles, and pinworms, the recommended dose is 2.3 mg/lb (5 mg/kg).

For control of hypobiotic (encysted early 3rd stage), late 3rd stage, and 4th stage cyathostome larvae, 4th stage *Strongylus vulgaris* larvae, and 4th stage *Triodontophorus* larvae, the recommended dose is 4.5 mg/lb (10 mg/kg) daily for 5 consecutive days, administered one syringe for each 550 lb body weight per day. 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.

DIRECTIONS FOR USE:
1. Determine the weight of the horse.
2. Remove syringe tip.
3. Insert the diluting liquid into the edge of the ring nearest the tip lines with the syringe.
4. Draw the plunger to advance paste to tip.
5. Set the diluting ring at the graduation nearest the weight of the horse for the dosage rate of 5 mg/kg. For the dosage rate of 10 mg/kg, set the diluting ring 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.

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

HOW SUPPLIED:
Safe-Guard[®] Paste 10% Equine Dewormer is supplied in 25 gram syringes.

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

Fenbendazole (active ingredient) made in China. Formulated in France.

Distributed by:
Merck Inc. (d/b/a Merck Animal Health)
Madison, NJ 07940

Approved by FDA under NADA # 120-648

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Rev. 8/21

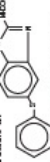


safe-guard[®]

(fenbendazole)

Paste 10% (100 mg/g) Equine Dewormer

DESCRIPTION:
Safe-Guard[®] (fenbendazole) Paste 10% contains the active antihelminthic, fenbendazole. The chemical name is 5-(2-phenyl-1H-imidazol-5-yl)-2-benzimidazole carboxamide. 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.

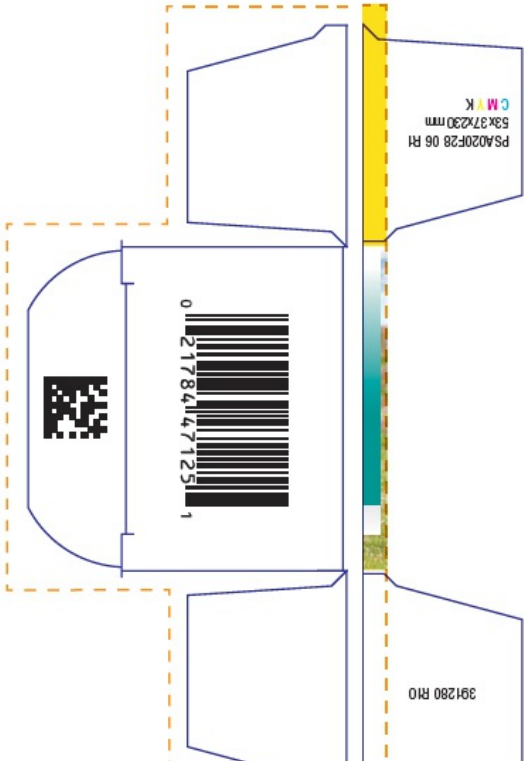
INDICATIONS:
Safe-Guard[®] Paste 10% is indicated for the treatment and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascariids (*Parascaris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

PRECAUTIONS:
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 227 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 hypersensitivity reaction. As with any drug, these reactions should be treated symptomatically. 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, 4.5 mg/lb (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 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-FDA/ETS, or <http://www.fda.gov/reportmalas>.

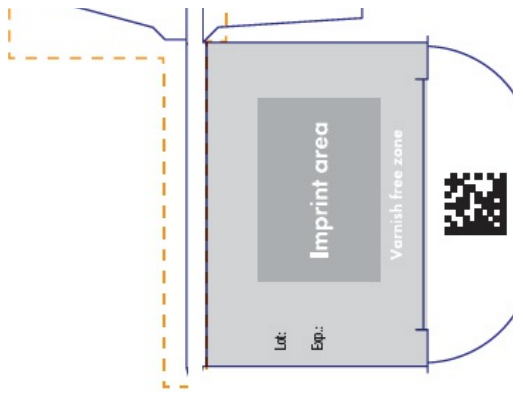
OTHER WARNINGS: Do not use in horses intended for human consumption.

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.



PSA020F28 06 RI
53x37x230 mm
CMK

391280 R10



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



CON SULTY VETERN VIKMAN F ON ASSISTANCE IN THE MANOSIS, TREATMENT AND COLMOLO PARASITISM
SAFEGUARD PASTE FOR ORES FOR USE
TREATING HORSES (Colic) - use only as directed.
This paste is intended for use only as directed. It is not intended for use in other species.
SAFEGUARD PASTE FOR ORES FOR USE
TREATING HORSES (Colic) - use only as directed.
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SAFEGUARD PASTE FOR ORES FOR USE
TREATING HORSES (Colic) - use only as directed.
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safe-guard®

(fenbendazole)

Net Weight 290 g (10.2 oz)

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.



safe-guard®

(fenbendazole)

Net Weight 290 g (10.2 oz)

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.



safe-guard®

(fenbendazole)

Net Weight 290 g (10.2 oz)

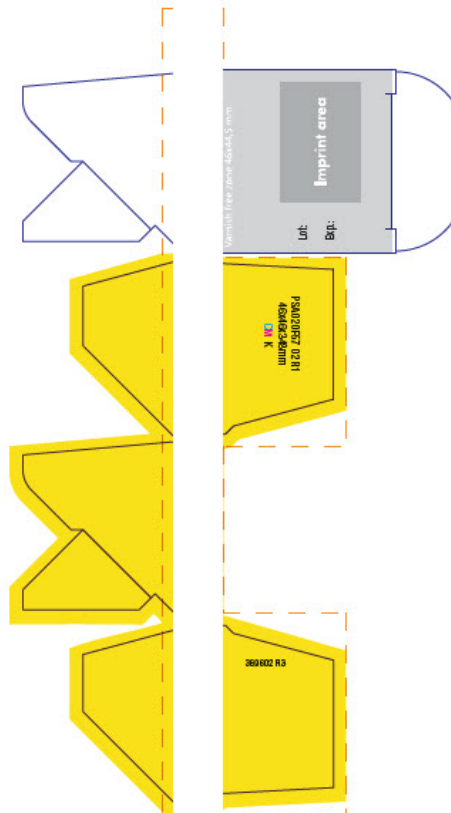
Fenbendazole (active ingred.) made in China.
Formulated in France.

Distributed by:
Intervet Inc. (a/b/a Merck Animal Health)
Madison, NJ 07940

Approved by FDA under NADA # 132-872
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Rev. 09/2020



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SAFE-GUARD

fenbendazole paste

Product Information

Product Type

OTC ANIMAL DRUG

Item Code (Source)

NDC:57926-083

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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C00X)	
Sorbitol (UNII: 506T60A25R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0K00R)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

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:57926-083-44	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

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-084
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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C00X)	
Sorbitol (UNII: 506T60A25R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

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:57926-084-46	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

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C00X)	
Sorbitol (UNII: 506T60A25R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

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	

Labeler - Merck Sharp & Dohme (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Intervet Production S.A.		771867553	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Apeloia Kangyu Pharmaceutical Co., Ltd.		420823163	API MANUFACTURE