SAFE-GUARD- fenbendazole suspension Merck Sharp & Dohme Corp.

Reference Label Set Id: 93c3abe2-5d4b-4d90-ac25-b2078026629e

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safe-guard® (fenbendazole) Dewormer

**INDICATIONS:** Beef and Dairy Cattle - 2.3 mg/lb (5 mg/kg) body weight 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 & 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*).

**Goats** - 2.3 mg/lb (5 mg/kg) body weight for the treatment and control of: **Stomach worms** (adults): *Haemonchus contortus* and *Teladorsagia circumcincta*.

**DIRECTIONS:** Administer orally. The recommended dose of 2.3 mg/lb (5 mg/kg) of body weight is achieved when 2.3 mL of the drug are given for each 100 lb body weight.

#### **EXAMPLES:**

Cattle:		Goats:		
Body Weight	Amount	Body Weight	Amount	
100 lb	2.3 mL	25 lb	0.6 mL	
200 lb	4.6 mL	50 lb	1.2 mL	
300 lb	6.9 mL	75 lb	1.7 mL	
400 lb	9.2 mL	100 lb	2.3 mL	
500 lb	11.5 mL	125 lb	2.9 mL	
1000 lb	23.0 mL			
1500 lb	34.5 mL			

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.

**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: 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.

Store at or below 25°C (77°F).

Protect from freezing. Shake well before use.

Restricted drug (California) - use only as directed.

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

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

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#### PRINCIPAL DISPLAY PANEL - 3,785 mL Bottle Label

safe-guard<sup>®</sup> (fenbendazole)

Dewormer

367235 R3

for Beef & Dairy Cattle and Goats

Suspension 10% (100 mg/mL)

Withdrawal Periods and Residue Warnings: Milk taken from cows during treatment and for 48 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.

Goats must not be slaughtered for human consumption within 6 days following last treatment with this drug product. Because a milk discard time has not been established, do not use in lactating goats.

Consult your veterinarian for assistance in the diagnosis,

treatment and control of parasitism.

LOT NUMBER: EXPIRATION DATE:

1 Gallon (3,785 mL)

MERCK Animal Health

386508 R4



LOT NUMBER:

imprint area

EXPIRATION DATE:





# Dewormer

for Beef & Dairy Cattle and Goats

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1 Gallon (3,785 mL)





386508 R4



# **Dewormer**



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Goats - 2.3 mg/lb (5 mg/kg) body weight for the treatment and control of: Stomach worms (adults): Haemonchus contortus and Teladorsagia circumcincta.

DIRECTIONS: Administer orally. The recommended dose of 2.3 mg/lb (5 mg/kg) of body weight is achieved when 2.3 mL of the drug are given for each 100 lb body weight.

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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.

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 <a href="http://www.fda.gov/reportanimalae">http://www.fda.gov/reportanimalae</a>.

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Distributed by: Intervet Inc (d/b/a Merck Animal Health), Madison,

Approved by FDA under NADA # 128-620

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Rev. 09/20









#### **SAFE-GUARD**

fenbendazole suspension

#### **Product Information**

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:57926-088

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 mL

#### **Inactive Ingredients**

Ingredient Name	Strength
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
povidone, unspecified (UNII: FZ 989GH94E)	
Avia a dissua aitura ta dibudurata (UNU), DOOF (7DOF/)	

trisodium citrate dihydrate (UNII: B22547B95K) citric acid monohydrate (UNII: 2968PHW8QP)

water (UNII: 059QF0KO0R)

# **Packaging**

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#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:57926-088-01	3785 mL in 1 BOTTLE				
2	NDC:57926-088-02	1000 mL in 1 BOTTLE				
3	NDC:57926-088-03	10000 mL in 1 BOTTLE				

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA128620	09/20/1983		
147 167 1	14 15/122020	03/20/1303		

## Labeler - Merck Sharp & Dohme Corp. (001317601)

# **Establishment**

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

Revised: 9/2021 Merck Sharp & Dohme Corp.