SAFE-GUARD- fenbendazole powder
Schering Corporation

Safe-guard®
(fenbendazole)
Dewormer
20% Type A Medicated Article

CATTLE: Dairy and Beef Cattle

SWINE: Growing pigs, gilts, pregnant sows and boars

HORSES

Zoo and Wildlife Animals

Growing Turkeys

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS.
FOR USE IN MANUFACTURED FEEDS ONLY.

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).

INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil.

CATTLE: Dairy and Beef 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*).

DRUG FEEDING RATE:

5 mg fenbendazole per kg body weight in a one (1) day treatment (2.27 mg fenbendazole per pound).

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.

MIXING DIRECTIONS:

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated cattle feed according to the table below to obtain the proper concentration in the Type B

medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Cattle Type B Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
11.04	1,001 (0.5)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated cattle feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.

The following table gives examples of how some complete Type C medicated feeds can be prepared:

Cattle Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
2.20	200 (0.1)
11.02	1,000 (0.5)

FEEDING DIRECTIONS:

Feed as the sole ration for one (1) day. No prior withdrawal of feed or water necessary. Type C medicated cattle feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

FREE-CHOICE FEEDS: Type C free-choice medicated feed must be manufactured by a licensed feed mill according to an approved formula to provide a total of 5 mg per kg body weight fenbendazole over 3 to 6 days.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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.

Withdrawal Periods and Residue Warnings: Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 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.

SWINE: Growing pigs, gilts, pregnant sows, and boars

FOR THE TREATMENT AND CONTROL OF:

Lungworms: Adult *Metastrongylus apri,* adult *Metastrongylus pudendotectus*; **Gastrointestinal worms:** Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (*Ascaris suum*), Adult nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*), Adult small stomach worms (*Hyostrongylus rubidus*), Adult and larvae (L2, L3, L4 stages - intestinal mucosal forms) whipworms (*Trichuris suis*); and **Kidney worms:** Adult and larvae *Stephanurus dentatus*.

DRUG FEEDING RATE:

9 mg fenbendazole per kg body weight (4.08 mg fenbendazole per pound) to be fed as the sole ration over a period of 3 to 12 days.

MIXING DIRECTIONS:

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated swine feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Swine Type B Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
11.03	1,000 (0.5)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated swine feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.

The following table gives examples of how some complete Type C medicated feeds can be prepared:

Swine Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.11	10 (0.005)
3.31	300 (0.15)

FEEDING DIRECTIONS:

Feed as the sole ration for three (3) to twelve (12) consecutive days. No prior withdrawal of feed or water necessary.

Type C medicated swine feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

***Withdrawal Periods*:** Swine must not be slaughtered for human consumption within 4 days following last treatment with this drug product.

HORSES

FOR THE TREATMENT AND CONTROL OF:

Large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), **Small strongyles** (*Cyathostomum* spp., *Cylicocyclus spp., Cylicostephanus spp.),* **Pinworms** *(Oxyuris equi),* **Ascarids** *(Parascaris equorum).*

DRUG FEEDING RATE:

For the control of large strongyles, small strongyles, and pinworms the recommended dose is 5 mg fenbendazole per kg body weight (2.27 mg fenbendazole per pound) in a one (1) day treatment. For the control of ascarids the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg fenbendazole per pound) in a one (1) day treatment.

All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed.

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.

MIXING DIRECTIONS:

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated horse feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Equine Type B Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
110.25	10,000 (5.0)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® Type A medicated article with equine feed according to the table below to obtain the proper concentration in the Type C medicated feed:

Equine Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
50.05	4,540 (2.27)

FEEDING DIRECTIONS:

No prior withdrawal of feed or water necessary. Type C medicated horse feed containing SAFE-GUARD® 20% can also be fed pelleted.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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.

Do not use in horses intended for human consumption.

Approved by FDA under NADA # 131-675

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

STORE AT OR BELOW 25°C (77°F). EXCURSIONS UP TO 40°C (104°F) ARE PERMITTED.

SEE OTHER SIDE FOR ZOO AND WILDLIFE ANIMALS AND GROWING TURKEYS.

Net Weight 25 pounds (11.34 kg)

Lot / Expiration date located below:

364857 R15

Zoo and Wildlife Animals

FOR THE TREATMENT AND CONTROL OF:

Internal parasites in hoofed zoo and wildlife animals (see dosage section for specific parasites, animal species and required doses).

DRUG FEEDING RATES:

Host Animal	**Recommended Treatment For**	**mg Fenbendazole/kg Body Wt./Day × Days of Treatment**
Bighorn sheep (*Ovis canadensis canadensis*)	**Lungworms:** (*Protostrongylus* spp.)	10 mg/kg/day × 3 days
Feral swine	**Kidney worms:** (*Stephanurus dentatus*), **Roundworms:**(*Ascaris*	

Feral swine (*Sus scrofa*)	*suum*), **Nodular worms:** (*Oesophagostomum dentatum*)	3 mg/kg/day × 3 days
Ruminants – subfamily antilopinae: Persian gazelles (*Gazella subgutturosa subgutturosa*) Addra gazelle (*Gazella dama ruficollis*) Slendorhorn gazelle (*Gazella leptoceros*) Kenya impala (*Aepyceros melampus rendilis*) Roosevelt's gazelle (*Gazella granti roosevelti*) Indian blackbuck (*Antilope cervicapra*) Mhorr gazelle (*Gazella dama mhorr*) Thomson's gazelles (*Gazella thomsoni thomsoni*) **Ruminants – subfamily hippotraginae:** Addax (*Addax nasomaculatus*) Angolan roan antelope (*Hippotragus equinus cottoni*) Fringed-ear oryx (*Oryx gazelle callotis*) Arabian oryx (*Oryx leucoryx*) **Ruminants – subfamily caprinae:** Armenian mouflon	**Small stomach worms:** (*Trichostrongylus* spp.), **Thread-necked intestinal worms:** (*Nematodirus* spp.), **Barberpole worms:** (*Haemonchus* spp.), **Whipworms:** (*Trichuris* spp.)	2.5 mg/kg/day × 3 days

(*Ovis orientalis gmelini*) Russian saiga (*Saiga tatarica*)		

It is recommended that the user exercise judgmental expertise as needed for retreatment within six (6) weeks. This would depend upon the conditions of continued exposure to parasites, condition of treated animals, and ambient temperatures.

MIXING DIRECTIONS:

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated zoo/wildlife animal feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.

The following table gives examples of how some complete Type C medicated feeds can be prepared:

Feral Swine, Wildlife and Zoo Ruminants & Bighorn Sheep Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.55	50 (0.025)
11.02	1,000 (0.5)

FEEDING DIRECTIONS:

Type C medicated feeds containing SAFE-GUARD®20% can be fed in either a mash or pelleted form. No prior withdrawal of feed or water is necessary.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

RESIDUE WARNING: Do not use 14 days before or during the hunting season.

Growing Turkeys

FOR THE TREATMENT AND CONTROL OF:

Gastrointestinal worms: Roundworms, Adults and larvae (*Ascaridia dissimilis*); Cecal worms, Adults and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).

DRUG FEEDING RATE:

14.5 g fenbendazole/ton of feed, to be fed as the sole ration for 6 days.

MIXING DIRECTIONS:

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated turkey feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives an example of how some Type B medicated feed concentrations can be prepared:

Turkey Type B Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
5.51	500 (0.25)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated growing turkey feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.

The following table describes how to obtain the proper concentration in the complete Type C medicated feed:

Turkey Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.16	14.5 (0.007)

FEEDING DIRECTIONS:

Medicated feed containing fenbendazole should be fed as the sole ration for six (6) consecutive days to growing turkeys only. No prior withdrawal of feed or water necessary. Type C medicated growing turkey feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

Withdrawal Periods: No withdrawal period is required when used according to labeling.

SEE OTHER SIDE FOR CATTLE, SWINE, AND HORSES.

MERCK
Animal Health

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

Rev. 09/2020

PRINCIPAL DISPLAY PANEL - 11.34 kg Bag Label

TO OPEN-PULL NARROW TAPE

safe-guard®
(fenbendazole)

Dewormer

20% Type A
Medicated Article

CATTLE: Dairy and Beef Cattle

SWINE: Growing pigs, gilts, pregnant sows and boars

HORSES

Zoo and Wildlife Animals

Growing Turkeys

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS.
FOR USE IN MANUFACTURED FEEDS ONLY.

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).
INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil.

TO OPEN-PULL NARROW TAPE

safe-guard® (fenbendazole)

Dewormer

20% Type A Medicated Article

CATTLE: Dairy and Beef Cattle
SWINE: Growing pigs, gilts, pregnant sows and boars
HORSES
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MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS.
FOR USE IN MANUFACTURED FEEDS ONLY.

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).
INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil.

CATTLE: Dairy and Beef 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*).

DRUG FEEDING RATE:
5 mg fenbendazole per kg body weight in a one (1) day treatment (2.27 mg fenbendazole per pound).
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.

MIXING DIRECTIONS:
Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated cattle feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Cattle Type B Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
11.04	1,001 (0.5)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated cattle feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.
The following table gives examples of how some complete Type C medicated feeds can be prepared:

Cattle Type C Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
2.20	200 (0.1)
11.02	1,000 (0.5)

FEEDING DIRECTIONS:
Feed as the sole ration for one (1) day. No prior withdrawal of feed or water necessary. Type C medicated cattle feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

FREE-CHOICE FEEDS: Type C free-choice medicated feed must be manufactured by a licensed feed mill according to an approved formula to provide a total of 5 mg per kg body weight fenbendazole over 3 to 6 days.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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

SWINE: Growing pigs, gilts, pregnant sows, and boars

FOR THE TREATMENT AND CONTROL OF:
Lungworms: Adult *Metastrongylus spp.* adult *Metastrongylus pudendotectus*; **Gastrointestinal worms:** Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (*Ascaris suum*), Adult nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*), Adult small stomach worms (*Hyostrongylus rubidus*), Adult and larvae (L2, L3, L4 stages - intestinal mucosal forms) whipworms (*Trichuris suis*); and **Kidney worms:** Adult and larvae *Stephanurus dentatus*.

DRUG FEEDING RATE:
9 mg fenbendazole per kg body weight (4.08 mg fenbendazole per pound) to be fed as the sole ration over a period of 3 to 12 days.

MIXING DIRECTIONS:
Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated swine feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Swine Type B Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
11.03	1,000 (0.5)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated swine feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.
The following table gives examples of how some complete Type C medicated feeds can be prepared:

Swine Type C Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.11	10 (0.005)
3.31	300 (0.15)

FEEDING DIRECTIONS:
Feed as the sole ration for three (3) to twelve (12) consecutive days. No prior withdrawal of feed or water necessary.
Type C medicated swine feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

Withdrawal Periods: Swine must not be slaughtered for human consumption within 4 days following last treatment with this drug product.

HORSES

FOR THE TREATMENT AND CONTROL OF:
Large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), **Small strongyles** (*Cyathostomum* spp., *Cylicocyclus spp., Cylicostephanus spp.*), **Pinworms** (*Oxyuris equi*), **Ascarids** (*Parascaris equorum*).

DRUG FEEDING RATE:
For the control of large strongyles, small strongyles, and pinworms the recommended dose is 5 mg fenbendazole per kg body weight (2.27 mg fenbendazole per pound) in a one (1) day treatment. For the control of ascarids the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg fenbendazole per pound) in a one (1) day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed.
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.

MIXING DIRECTIONS:
Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated horse feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives examples of how some Type B medicated feed concentrations can be prepared:

Equine Type B Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
110.25	10,000 (5.0)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® Type A medicated article with equine feed according to the table below to obtain the proper concentration in the Type C medicated feed:

Equine Type C Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
50.05	4,540 (2.27)

FEEDING DIRECTIONS:
No prior withdrawal of feed or water necessary. Type C medicated horse feed containing SAFE-GUARD® 20% can also be fed pelleted.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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.

Do not use in horses intended for human consumption.

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CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE

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.

Withdrawal Periods and Residue Warnings: Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 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.

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM.
STORE AT OR BELOW 25°C (77°F). EXCURSIONS UP TO 40°C (104°F) ARE PERMITTED.
SEE OTHER SIDE FOR ZOO AND WILDLIFE ANIMALS AND GROWING TURKEYS.

Net Weight 25 pounds (11.34 kg)

Lot / Expiration date located below:

364857 R15

safe-guard® (fenbendazole) Dewormer

20% Type A Medicated Article

CATTLE: Dairy and Beef Cattle
SWINE: Growing pigs, gilts, pregnant sows and boars
HORSES
Zoo and Wildlife Animals
Growing Turkeys

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS.
FOR USE IN MANUFACTURED FEEDS ONLY.

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).
INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil.

Zoo and Wildlife Animals

FOR THE TREATMENT AND CONTROL OF:
Internal parasites in hoofed zoo and wildlife animals (see dosage section for specific parasites, animal species and required doses).

DRUG FEEDING RATES:

Host Animal	Recommended Treatment For	mg Fenbendazole/kg Body Wt./Day x Days of Treatment
Bighorn sheep (*Ovis canadensis canadensis*)	Lungworms: (*Protostrongylus* spp.)	10 mg/kg/day x 3 days
Feral swine (*Sus scrofa*)	Kidney worms: (*Stephanurus dentatus*), Roundworms: (*Ascaris suum*), Nodular worms: (*Oesophagostomum dentatum*)	3 mg/kg/day x 3 days
Ruminants – subfamily antilopinae: Persian gazelles (*Gazella subgutturosa subgutturosa*) Addra gazelle (*Gazella dama ruficollis*) Slenderhorn gazelle (*Gazella leptoceros*) Kenya impala (*Aepyceros melampus rendilis*) Roosevelt's gazelle (*Gazella granti roosevelti*) Indian blackbuck (*Antilope cervicapra*) Mhorr gazelle (*Gazella dama mhorr*) Thomson's gazelles (*Gazella thomsoni thomsoni*)	Small stomach worms: (*Trichostrongylus* spp.), Thread-necked intestinal worms: (*Nematodirus* spp.), Barberpole worms: (*Haemonchus* spp.), Whipworms: (*Trichuris* spp.)	2.5 mg/kg/day x 3 days
Ruminants – subfamily hippotraginae: Addax (*Addax nasomaculatus*) Angolan roan antelope (*Hippotragus equinus cottoni*) Fringed-ear oryx (*Oryx gazella callotis*) Arabian oryx (*Oryx leucoryx*) **Ruminants – subfamily caprinae:**		

Growing Turkeys

FOR THE TREATMENT AND CONTROL OF:
Gastrointestinal worms: Roundworms, Adults and larvae (*Ascaridia dissimilis*); Cecal worms, Adults and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).

DRUG FEEDING RATE:
14.5 g fenbendazole/ton of feed, to be fed as the sole ration for 6 days.

MIXING DIRECTIONS:
Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated turkey feed according to the table below to obtain the proper concentration in the Type B medicated feed. The following table gives an example of how some Type B medicated feed concentrations can be prepared:

Turkey Type B Medicated Feed Instructions	
Pounds of Type A Medicated Article to Add per Ton of Feed to Make a Type B Medicated Feed	Resulting Fenbendazole Concentration in Type B Medicated Feed [grams/ton (grams/pound)]
5.51	500 (0.25)
195.59	17,740 (8.9)

Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated growing turkey feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.

Armenian mouflon (*Ovis orientalis gmelini*)		
Russian saiga (*Saiga tatarica*)		

It is recommended that the user exercise judgmental expertise as needed for retreatment within six (6) weeks. This would depend upon the conditions of continued exposure to parasites, condition of treated animals, and ambient temperatures.

MIXING DIRECTIONS:
Thoroughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated zoo/wildlife animal feed according to the table below to obtain the proper concentration in the complete Type C medicated feed. Prepare an intermediate pre-blend of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feed ingredients (a dilution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix this pre-blend with the rest of the feed ingredients to ensure complete and uniform distribution of the Type A medicated article.
The following table gives examples of how some complete Type C medicated feeds can be prepared:

Feral Swine, Wildlife and Zoo Ruminants & Bighorn Sheep Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.55	50 (0.025)
11.02	1,000 (0.5)

FEEDING DIRECTIONS:
Type C medicated feeds containing SAFE-GUARD® 20% can be fed in either a mash or pelleted form. No prior withdrawal of feed or water is necessary.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS.
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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

▶ **RESIDUE WARNING:** Do not use 14 days before or during the hunting season. ◀

The following table describes how to obtain the proper concentration in the complete Type C medicated feed:

Turkey Type C Medicated Feed Instructions

Pounds of Type A Medicated Article to Add per Ton to Make a Type C Medicated Feed	Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
0.16	14.5 (0.007)

FEEDING DIRECTIONS:
Medicated feed containing fenbendazole should be fed as the sole ration for six (6) consecutive days to growing turkeys only. No prior withdrawal of feed or water necessary. Type C medicated growing turkey feeds containing SAFE-GUARD® 20% can be fed pelleted or as a meal.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. 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. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring.

▶ ***Withdrawal Periods:*** No withdrawal period is required when used according to labeling. ◀

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM.
STORE AT OR BELOW 26°C (77°F). EXCURSIONS UP TO 40°C (104°F) ARE PERMITTED.
SEE OTHER SIDE FOR CATTLE, SWINE, AND HORSES.

Net Weight 25 pounds (11.34 kg)

Approved by FDA under NADA # 131-675

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

Rev. 09/2020

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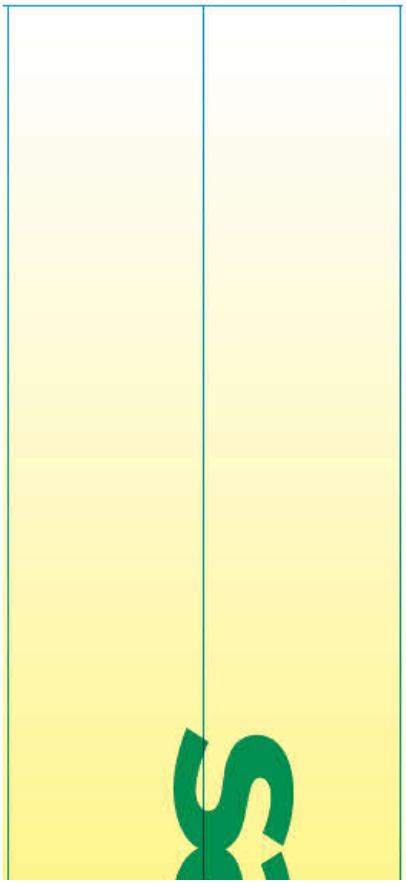
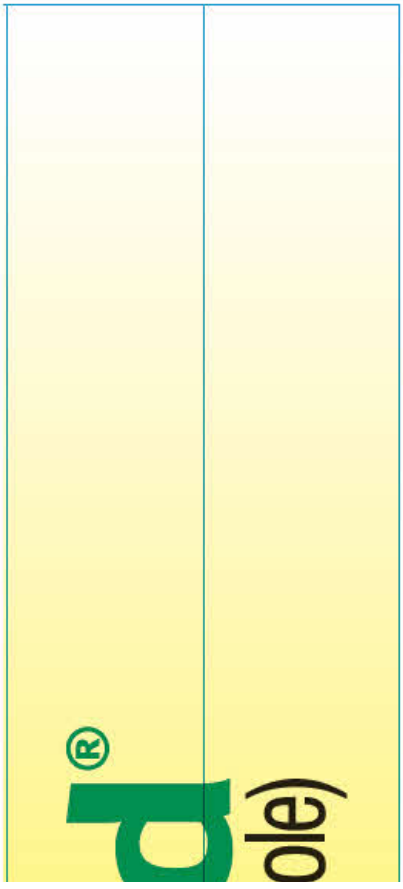
364857 R15





SAFE-GUARD

fenbendazole powder

Product Information			
Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:57926-090

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Fenbendazole (UNII: 621BVT9M36) (Fenbendazole - UNII:621BVT9M36)	Fenbendazole	200 g in 1 kg

Inactive Ingredients

Ingredient Name	Strength
Mineral Oil (UNII: T5L8T28FGP)	
Calcium Carbonate (UNII: H0G9379FGK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-090-25	1 in 1 BAG		
1		11.34 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA131675	01/31/1984	

Labeler - Schering Corporation (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
ADM Alliance Nutrition, Inc.		834721284	MEDICATED ANIMAL FEED MANUFACTURE

Establishment

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

Revised: 2/2022 Schering Corporation