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:

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)

Cattle Type B Medicated Feed Instructions

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:

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)

Cattle Type C Medicated Feed Instructions

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 <u>http://www.fda.gov/reportanimalae.</u>

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:

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)

Swine Type B Medicated Feed Instructions

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:

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)

Swine Type C Medicated Feed Instructions

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 $^{\ensuremath{\mathbb{R}}}$ 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 <u>http://www.fda.gov/reportanimalae.</u>

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 <u>http://www.fda.gov/reportanimalae.</u>

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 (<i>Ovis</i> canadensis canadensis)	Lungworms: (Protostrongylus spp.)	10 mg/kg/day × 3 days
Foral swine	Kidney worms: (Stephanurus dentatus), Roundworms:(Ascaris	

(Sus scrofa)	suum), Nodular worms: (Oesophagostomum dentatum)	3 mg/kg/da	y × 3 days
Ruminants - subfamily antilopinae: Persian gazelles (<i>Gazella</i> subgutturosa subgutturosa) Addra gazelle (<i>Gazella dama</i> ruficollis) Slendorhorn gazelle (<i>Gazella leptoceros</i>) Kenya impala (<i>Aepyceros</i> melampus rendilis) Roosevelt's gazelle	Small stomach worms: (<i>Trichostrongylus</i> spp.), Thread-necked intestinal worms: (<i>Nematodirus</i> spp.), Barberpole worms: (<i>Haemonchus</i> spp.), Whipworms: (<i>Trichuris</i> spp.)	2.5 mg/kg/d	ay × 3 days
(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	•	,	

(Ovis orientalis gmelini)	
Russian saiga (<i>Saiga tatarica</i>)	

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 <u>http://www.fda.gov/reportanimalae.</u>

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 <u>http://www.fda.gov/reportanimalae.</u>

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

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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.





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 OII.

CATTLE: Dairy and **Beef Cattle**

FOR THE TREATMENT AND CONTROL OF

FUR THE THEATMENT AND CONTINUE OF: Lungwoma: Adult Delyocaulas vinjarais; Stomach worms: Adult bro stomach worms (*Asternagia astertigi*), Adult and fourth stage larvae barbarpole worms (*Hamonchus contritus*), fundetinal worme (*Adult and* fourth stage larvae); hookeworm (*Burostrumur philo tomanu*), thread-necked intestinal worms (*Nematodrus heivetianus*), smal ich worms: Adult brown intestinal worms (Cooperá punctata & C. oncophora), sana intestinal worms (Cooperá punctata & C. oncophora), banknipt worms (Trichestrongylus colubriformis), and nodular worms (Oscophagostomum radiatum).

DRUG FEEDING BATE

5 mg fenbendacole per kg body weight in a one (1) day treatment (2.27 mg fenbendacole per pound). Do not underdose. Ensure each animal receives a complete does 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

Cattle Type B Medica	ted Feed Instructions
Pounds of Type A Medicated Article to Add per Ton of Feed	Resulting Fenbendazole Concentration In Type B
to Make a Type B Medicated Feed	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 Thoroughly mix SAH-E-GUARID® 20% Type A medicated article with non-medicated cattle field according to the table below to obtain the proper concentration in the complete Type C medicated field. Prepare an intermedicate pre-blend of the Type A medicated article prior to moting in a complete field. Thoroughly mix the required amount of Type A medicated article in a convenient quantity of feel ingredients (a dilution of one part Type A medicated article and rine parts grain cartier 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 federation can be also mercine on the cartier 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 Medic	ated 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)]
220	200 (0.1)
11.02	1,000 (0.5)

Feed as the sole ration for one (1) day. No prior withdrawal of feed or water necessary. Type C medicated cattle feeds containing SAFE-GUARD⁶ 20% can be fed pelleted or as a meel.

FREE-CHCICE FEEDS: Type C free-choice medicated feed must be manufactured by a losnesd feed mill according to an approved formula to provide a total of 5 mg per kg body weight fenbendazole over 3 to 6 days. provide a total of a mg per kg body weight tembendation over a too day WAINING: KEEP THIS AND ALL DRUGS OUT OF THE FREACH OF CHILDREN. NOT FOR USE IN HUMANS. The Stafety Data Sheet (SDS) contains more deliated 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 devormer, and has been reported for most classes of dewormers. Treatment with a and has been reported for most classes of devernees, resulting with a deverneer used in conjunction with paradise management practices appropriate to the geographic area and the animal(s) to be treated may sow the development of parasite resistance. Facel examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the heart, 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

FUN THE TREAMENT AND CONTINUE DE: Lungworms: Adult Marstongylos april adult Metastrongylus pudendo tectus; Gastrointestinal worms: Adult and larvée (13, L4 stages, liver, lung, intestinal forms) large roundworms (Acadis suvuh), Adult nodular worms (Ossophagostonum dentatum, 0, quadrispinatatum), Adult small stomach worms (Apostrongylus rabidas), Adult ad larven (L2, L3, L4 stages - Intestina mucosal forms) whipworms (Trichuris suis); and Kidney worms: Adult and Insee, Bronbergens, dentatur, 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

MIAINED UNICC-TIONS: Throughly mix SAFE-GUARD® 20% Type A medicated article with non-medicated same 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 Medica	ted 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)

165.59 17/.40 (8.9) Thorough unit SAFE-GUARD® 20%. Type A medicated article with non-medicated same faed according to the table below to obtain the proper-concentration in the complete Type C medicated feed. Proper earlier that more kited of the Type A medicated article prior to mixing in a complete feed. Thoroughly mix the required amount of Type A medicated article a nor-convenient quantity of feed ingredents to a diffuent 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 this have scenesce the processe samplets Tare C medicated

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

cated Feed Instructions
Resulting Fenbendazole Concentration in Type C Medicated Feed [grams/ton (grams/pound)]
10 (0.005)
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

elleted or as a meal.

peleted or as a meal. WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. The Safety Data Steet (SDS) contains more detailed occupational safety information; For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-800-211-5573. For additional information about adverse drug experience reporting for animal drugs, contact FOA at 1-888-FDAVETS, or <u>bttp://www.doa.gov/reportanims/ae</u>. 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 stronglies (Strongvios edentatus, S. equinus, S. vulgaris, Triodontophorus spp.), Stanill strongvies (Cvathostonrum spp., Cylicocyclus spp., Cylicostephanus spp.), Pinworms (Oxyunis equi), Ascarida (Parascaris equirorum).

DRUG FEEDING RATE:

DRUG FEEDING HALE: For the control of large strongyles, small strongyles, and pinworms the recommended does is 5 mg tenbendacole per kg body weight (2.27 mg fenbendacole per pound) in a one (1) day treatment. For the control of ascarids the recommended does is 10 mg tenbendacole per kg body weight (4.54 mg tenbendacole 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: MIXING UNECTIONS: Throughy mix SAFE-SUARD® 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

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

feed according to the table below to obtain the proper concentration in the Type C med

Equine Type C Medica	ted 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)

FFEDING DIRECTIONS

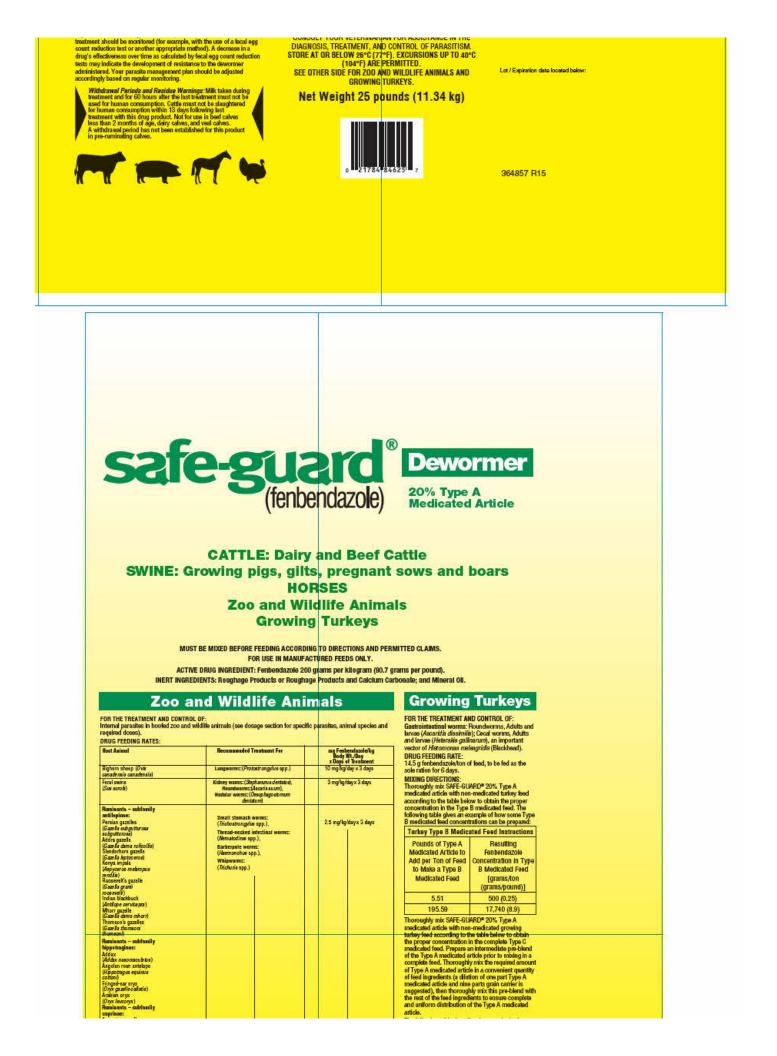
Precured Direct none: No prior withdrawal of feed or water necessary. Type C medicated horse feed containing SARE-GUARDP 20% can also be fed peliteted. WARNING: KEEP THIS AND ALL DRUSS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. The Safety Data Sheet (SOS) contains need for those in However, the same back back best contains need to the data of comparison a safety information. For customer service, acherse effects reporting, and/or a copy of the SDS, call 1-900-211-S273. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS, or http://www.fda.gov/reportanimalae.

OTHER WARMINGS: 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 slow me lowespinen or planate restants, recal soluritations of other diagnostic tests and paralise management history should be used to determine if the product is appropriate for the herd, prior to the use of any dewommer. Following the use of any dewommer, effectiveness of treatment should be monitored (for example, with the use of a facal agg count eduction lest or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal agg count reduction these manifolds the or endpendence and approximate mere to the descent 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 VOUD VETERINARIAN COR ASSISTANCE IN THE



Armenian (Ovis onie Russian s (Saige tat)	ntalis gmafin) aiga			Ļ		Ļ	
		20.01		1.7	 1.000	 	

would depend upon the conditions of continued exposure to parasites, condition of treated animals, and ambient tempe

temperatures. MIXING DIRECTIONS: Thorougity mix SAFE-GUARD® 20%. Type A medicated article with non-medicated zon/wildlife animal feed according to the table below to obtain the proper concentration in the complete Type C (medicated feed, Prepare an-intermediate problem 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 ingredientie (a diution of one part Type A medicated article and nine parts grain carrier is suggested), then thoroughly mix the pre-blend with the rest of the feed ingredients to ensure complete and uniform distibution 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 Resulting Fenbendazole Concentration In Type C

Medicated Feed			
[grams/ton (grams/pound)]			
50 (0.025)			
1,000 (0.5)			

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

withdraval 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 (SOS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the SUS, call 1-800-211-3573. For additional information about adverse frug septeince reporting for animal drugs, contact FDA at 1-888-FAVETS, or http://www.dda.gov/reportarimalee. 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 inonitored. A decrease of effectiveness overtime 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 de obtain the proper concentration in the complete Type C medicated feed:

Turkey Type C Medica	ated Feed Instructions
	Resulting Feribendazole
Medicated Article to	Concentration In Type
Add per Ton to Make	C Medicated Feed
a Type C Medicated	[grams/ton
Feed	(grams/pound)]
0.16	14.5 (0.007)

FEEDING DIRECTIONS

FEEDING DIRECTIONS: Medicated feed containing fentheradezole should be fed as the sole ration for six (6) consecutive days to growing tarkeys only. No prior withdrawal of feed or water necessary. Uppo E medicated growing turkey feeds containing SAFE-GUARD® 20% can be fed pelited or as a meal. WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANIS. 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 adverse drug seperience reporting for animal drugs, contact FDA at 1–888-FDW/ETS,

at 1-889-F0AVETS, or http://www.ida.gov/teportanimalea. OTHER WARNINGS: Parasite resistance may develop to any dewormer. All dewormers require accurate dosing for best resistic. 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 pansite management plan should be adjusted accordingly based on regular monitoring.

4

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 CATLLE, SWINE, AND HORSES.

Net Weight 25 pounds (11.34 kg)

Approved by FDA under NADA # 131-875

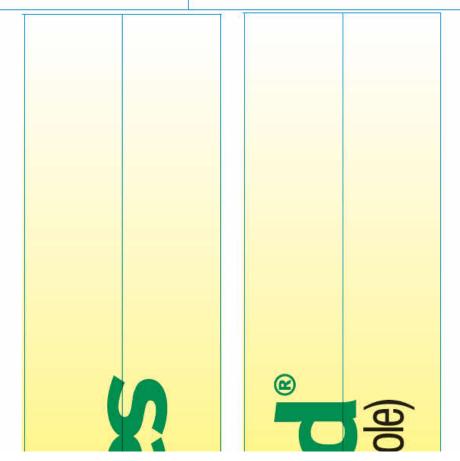
MERCK

Animal Health Distributed by: IntervetInc. (d/b/a Merck Animal Health) Medison, NJ 07040

62020 Intervat Inc., a subsidiary of Marck & Co. Inc. Madison, NJ 07040 Rev. 09/2020



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SAFE-GUARD			
fenbendazole powder			
Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-090

Active Ingree	dient/Act	ive Moiety				
	In	gredient Name		Basis d	of Strength	Strength
Fenbendazole (UNII: 621BVT	9M36) (Fenbendazole - UN	III:621BVT9M36)) Fenbenda	azole	200 g in 1 kg
Inactive Ingr	redients					
		Ingredient Name	e		St	rength
Mineral Oil (UNII:	: T5L8T28FG	P)				
Calcium Carbon	ate (UNII: H)G9379FGK)				
Calcium Carbon	ate (UNII: H)G9379FGK)				
Calcium Carbon	ate (UNII: H)G9379FGK)				
	ate (UNII: H)G9379FGK)				
Packaging		ckage Description	Marketing	Start Date	Marketin	g End Date
Packaging # Item Coc	de Pa	ckage Description	Marketing	Start Date	Marketin	g End Date
Packaging # Item Coc 1 NDC:57926-090	1e Pa 0-25 1 in 1	ckage Description	Marketing) Start Date	Marketin	g End Date
Packaging # Item Coc 1 NDC:57926-090	1e Pa 0-25 1 in 1	ckage Description	Marketing) Start Date	Marketin	g End Date
Calcium Carbon Packaging # Item Coc 1 NDC:57926-090 1	1e Pa 0-25 1 in 1	ckage Description	Marketing) Start Date	Marketin	g End Date
Packaging # Item Coc 1 NDC:57926-090	de Pa 0-25 1 in 1 11.34	ckage Description L BAG L kg in 1 BAG	Marketing	J Start Date	Marketing	g End Date
Packaging # Item Coc 1 NDC:57926-090	de Pa 0-25 1 in 1 11.34	ckage Description L BAG L kg in 1 BAG		Start Date		g End Date rketing End Date

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