PANACUR- fenbendazole granule Merck Sharp & Dohme Corp.

panacur[®] (fenbendazole)

For Dogs And For Only The Carnivorous/Omnivorous Animals Listed

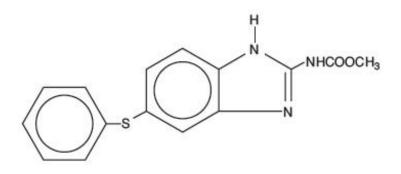
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Panacur[®] (fenbendazole) Granules 22.2% contains the active anthelmintic, fenbendazole. The chemical name of fenbendazole is methyl 5-(phenylthio)-2-benzimidazole carbamate.

The CAS Registry Number is 43210-67-9.

The chemical structure is:



Panacur[®] Granules 22.2% contains 222 mg/g of fenbendazole.

ACTIONS

The antiparasitic action of Panacur[®] Granules 22.2% is believed to be due to the inhibition of energy metabolism in the parasite.

FOR THE FOLLOWING CARNIVOROUS/OMNIVOROUS ANIMALS

Lions (*Panthera leo*), Tigers (*Panthera tigris*), Cheetahs (*Acinonyx jubatus*), Pumas (*Felis concolor*), Jaguars (*Panthera onca*), Leopards (*Panthera pardus*), Panthers (*Panthera spp.*), Grizzly Bears (*Ursus horribilis*), Polar Bears (*Ursus maritimus*), Black Bears (*Ursus americanus*)

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

INDICATIONS

Panacur[®] Granules 22.2% is used for control of the following internal parasites of the families <u>Felidae</u> and <u>Ursidae</u>.

<u>Felidae</u>: Lions (*Panthera leo*). For control of ascarids (*Toxocara cati, Toxascaris leonina*), hookworms (*Ancylostoma* spp.).

Tigers (Panthera tigris). For control of ascarids (Toxocara cati, Toxascaris leonina), hookworms

(Ancylostoma spp.).

Cheetahs (Acinonyx jubatus). For control of ascarids (Toxocara cati, Toxascaris leonina).

Pumas (*Felis concolor*), Panthers (*Panthera* spp.), Leopards (*Panthera pardus*), Jaguars (*Panthera onca*). For control of ascarids (*Toxocara cati, Toxascaris leonina*), hookworms (*Ancylostoma* spp.), tapeworms (*Taenia hydatigena, T. krabbei, T. taeniaeformis*).

<u>Ursidae</u>: Black Bears (*Ursus americanus*). For control of ascarids (*Baylisascaris transfuga, Toxascaris leonina*), hookworms (*Ancylostoma caninum*), tapeworms (*Taenia hydatigena, T. krabbei*).

Polar Bears (*Ursus maritimus*) and Grizzly Bears (*Ursus horribilis*). For control of ascarids (*Baylisascaris transfuga*, *Toxascaris leonina*).

DIRECTIONS

Efficacy is dependent on the correct dose level based on body weight over the appropriate treatment period. When possible, animals should be weighed to determine body weight accurately, otherwise weights can be estimated.

It is important that the appropriate dose of Panacur[®] be ingested. This may best be accomplished by applying the granules as a top dressing or mixing with a small portion of the food prior to offering the main meal.

Refer to the DOSAGE AND ADMINISTRATION portion of the labeling for determining the appropriate dose for each species of animal.

DOSAGE AND ADMINISTRATION

The dose for <u>Felidae</u> and <u>Ursidae</u> is 10 mg/kg BW daily for 3 consecutive days. Please see INDICATIONS for details as to claims for animal and parasite.

Directions: The daily dose of 10 mg/kg (4.54 mg/lb) can be achieved as follows:

Using a gram scale, weigh out 1 gram of Panacur[®] Granules 22.2% for each 22 kg or 50 lbs body weight.

TOXICOLOGY DATA

Panacur[®] has been fed to pregnant and non-pregnant females and to male animals including <u>Felidae</u> and <u>Ursidae</u> at ten times the recommended dose for twice the recommended treatment period without effect on reproduction. In one puma and one jaguar, ten times the recommended dose given for twice the recommended duration showed evidence of inappetence when administered the Panacur[®] Granules.

SIDE EFFECTS

In studies conducted in a variety of captive animals, loose stools have been reported in pumas, black bears, and ruminants. In one puma and one jaguar, periods of inappetence followed the initial consumption of fenbendazole at ten times the recommended treatment level.

DRUG REACTIONS

There are currently no data available to support the use of Panacur[®] Granules 22.2% in conjunction with other nutritional and drug substances in <u>Felidae</u> and <u>Ursidae</u>. However, experience with the drug under actual conditions of use has not revealed any incompatibilities with Panacur[®].

PRECAUTIONS

Medicated food must be fully consumed for Panacur[®] to be effective.

FOR DOGS

DOSAGE

50 mg/kg (22.7 mg/lb) daily for 3 consecutive days for the removal of ascarids (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

DIRECTIONS

The daily dosage of 50 mg/kg (22.7 mg/lb) can be achieved as follows:

Using a gram scale, weigh out 1 gram of Panacur[®] (fenbendazole) Granules 22.2% for each 4.44 kg or 10 lbs body weight.

Daily dosages must be repeated for 3 consecutive days. Mix the appropriate amount of drug with a small amount of the usual food: dry dog food may require slight moistening to facilitate mixing with the drug.

CONTRAINDICATIONS

None known.

TOXICOLOGY DATA

Panacur[®] Granules 22.2% did not cause toxicity when administered to weaned pups at doses equal to 5 times the recommended daily dose and for 2 times the duration of treatment.

ADVERSE REACTIONS

Another benzimidazole has been reported to cause hepatotoxicity clinically in canines. However, this effect has not been reported during the clinical use of fenbendazole. In US clinical studies, 3 of 240 dogs vomited which may have been drug related.

DRUG REACTIONS

Panacur[®] Granules 22.2% has been administered to dogs in clinical trials along with a wide variety of other drugs including antibiotics, steroids, anesthetics, tranquilizers, vitamins, and minerals. No incompatibilities with other drugs are known at this time.

PRECAUTIONS

Medicated food must be fully consumed to be effective. Dispensing containers must be labeled with drug identification and directions for use.

HOW SUPPLIED

Panacur[®] Granules 22.2% is supplied in 1 lb jars.

Keep this and all medication out of the reach of children.

Store at controlled room temperature 68-77°F (20-25°C).

Manufactured by: Intervet GesmbH Vienna, Austria

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

www.intervetusa.com Made in Austria

NADA # 121-473, Approved by FDA

PRINCIPAL DISPLAY PANEL - 454 g Jar Carton

MERCK Animal Health

panacur[®] (fenbendazole)

Dewormer

Granules 22.2% (222 mg/g)

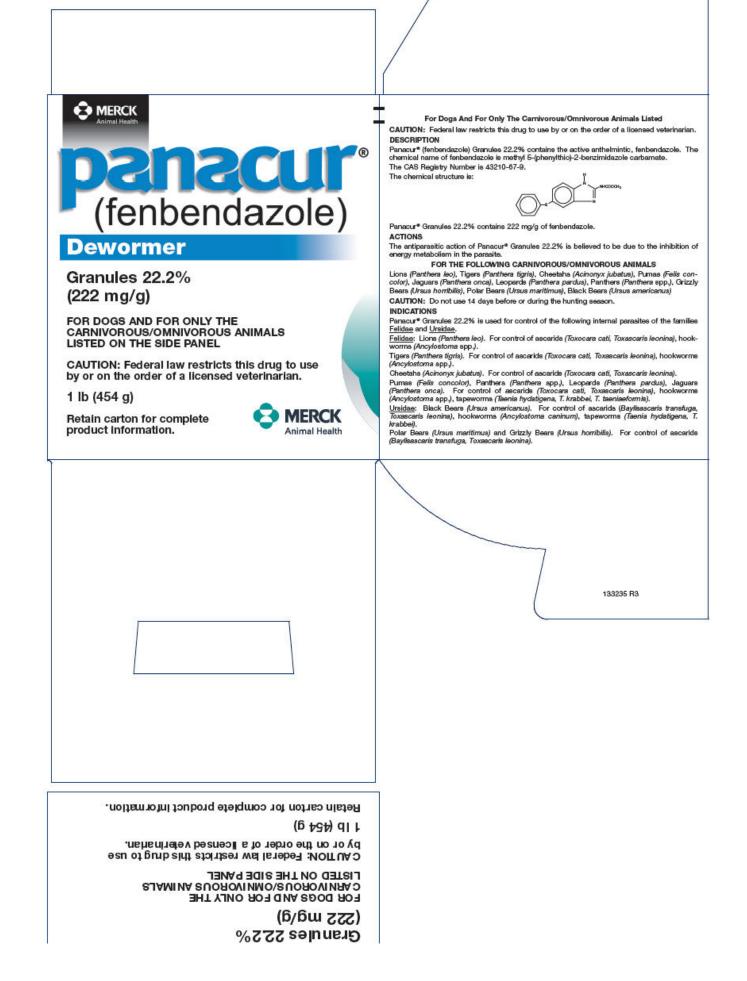
FOR DOGS AND FOR ONLY THE CARNIVOROUS/OMNIVOROUS ANIMALS LISTED ON THE SIDE PANEL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

1 lb (454 g)

Retain carton for complete product information.

MERCK Animal Health



Dewormer

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(fenbendazole)

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DIRECTIONS

Efficacy is dependent on the correct dose level based on body weight over the appropriate treat-ment period. When possible, animals should be weighed to determine body weight accurately, The daily dosage of 50 mg/kg (22.7 mg/lb) can be achieved as follows: Using a gram scale, weigh out 1 gram of Panacur[®] (fenbendazole) Granules 22.2% for each 4.44 kg or 10 lbs body weight. otherwise weights can be estimated. Daily dosages must be repeated for 3 consecutive days. Mix the appropriate amount of drug with a small amount of the usual food: dry dog food may require elight moistening to facilitate mixing with the drug. It is important that the appropriate dose of Panacur^a be ingested. This may best be accomplished by applying the granules as a top dressing or mixing with a small portion of the food prior to offering the main meal. Refer to the DOSAGE AND ADMINISTRATION portion of the labeling for determining the appro-CONTRAINDICATIONS priate dose for each species of animal None known DOSAGE AND ADMINISTRATION TOXICOLOGY DATA The dose for <u>Felidae</u> and <u>Ursidae</u> is 10 mg/kg BW daily for 3 consecutive days. Please see INDICATIONS for details as to claims for animal and parasite. Panacut[®] Granules 22.2% did not cause toxicity when administered to weaned pupe at doese equal to 5 times the recommended daily dose and for 2 times the duration of treatment. Directions: The daily dose of 10 mg/kg (4.54 mg/lb) can be achieved as follows: ADVERSE REACTIONS Using a gram scale, weigh out 1 gram of Panacur® Granules 22.2% for each 22 kg or 50 lbs Another benzimidazole has been reported to cause hepatotoxicity clinically in canines. However, this effect has not been reported during the clinical use of fenbendazole. In US clinical studies, 3 of 240 dogs vomited which may have been drug related. body weight. TOXICOLOGY DATA Panacur^a has been fed to pregnant and non-pregnant females and to male animals including <u>Felidae</u> and <u>Uraidae</u> at ten times the recommended does for twice the recommended treatment period without effect on reproduction. In one puma and one jaguar, ten times the recommended does given for twice the recommended duration showed evidence of inappetence when admin-DRUG REACTIONS Panacur* Granules 22.2% has been administered to dogs in clinical trials along with a wide variety of other drugs including antibiotics, steroids, aneethetics, tranquilizers, vitamins, and minerals. No incompatibilities with other drugs are known at this time. istered the Panacur[®] Granules. PRECAUTIONS SIDE EFFECTS Medicated food must be fully consumed to be effective. Dispensing containers must be labeled In studies conducted in a variety of captive animals, loose stools have been reported in purnas, with drug identification and directions for use. black beers, and ruminants. In one purna and one jaguar, periods of inappetence followed the initial consumption of fenbendazole at ten times the recommended treatment level. HOW SUPPLIED Panacur* Granules 22.2% is supplied in 1 lb jars. DRUG REACTIONS There are currently no data available to support the use of Panacur[®] Granules 22.2% in conjunction with other nutritional and drug substances in <u>Felidae</u> and <u>Ursidae</u>. However, experience with the drug under actual conditions of use has not revealed any incompatibilities with Panacur[®]. Keep this and all medication out of the reach of children. Store at controlled room temperature 68-77°F (20-25°C). Manufactured by: PRECAUTIONS Intervet GeembH Medicated food must be fully consumed for Panacur® to be effective. Vienna, Austria Distributed by: MERCK FOR DOGS Intervet Inc. DOSAGE (d/b/a Merck Animal Health) Animal Health 50 mg/kg (22.7 mg/lb) daily for 3 consecutive days for the removal of ascarids (Toxocara canis, Toxascaris leonina), hookworms (Ancylostoma caninum, Uncinaria stenocephala), whipworms (Trichuris vulpis), and tapeworms (Taenia pisiformis). Madison, NJ 07940 Lot: Exp: NADA # 121-473, www.intervetusa.com Approved by FDA Made in Austria





PANACUR			
fenbendazole granule			
Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:57926-474
Route of Administration	ORAL		

DIRECTIONS

Active Ingredient/Active Moiety								
Ingredient Name				Basis of Str	rength	Strength		
FENBENDAZOLE (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)) F	FENBENDAZOLE		222 mg in 1 g		
Packaging								
# Item Code	Package Description	Marketin	Marketing Start Date		Marketing End Date			
1 NDC:57926-474-20	1 in 1 CARTON							
1	454 g in 1 JAR							
Marketing Information								
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date			
NADA	ADA121473		0 1/0 5/19 79					

Labeler - Merck Sharp & Dohme Corp. (001317601)

Revised: 9/2015

Merck Sharp & Dohme Corp.