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 Felidae and Ursidae.

<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 $^{\text{(B)}}$ (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

Fenbendazole (active ingred.) Made in: see imprint. Formulated in Austria.

Approved by FDA under NADA # 121-473 Rev. 07/22

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

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.



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 app.), 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 Felidae and <u>Ursidae</u>.

Felidas: 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).

(Ancylostoma spp.), tapeworms (Taenia hydatigena, T. krabbei). T. taeniaeformis).

<u>Ursidae</u>: Black Bears (*Ursus americanus*). For control of ascarida (*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).

Retain carton for complete product information.

1 lb (454 g)

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

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

> > (222 mg/g)Granules 22.2%



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,

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 Felidae 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 Falidae and Uraidae at ten times the recommended dose for twice the recommended treatment period without effect on reproduction. In one puma and one igauer, 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 Felidae and Ursidae. However, experience with the drug under actual conditions of use has not revealed any incompatibilities with Panacure.

PRECAUTIONS

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

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).

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

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.

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:

Madison, NJ 07940

Fenbendazole (active ingred.)

Made in: see imprint. Formulated in Austria.

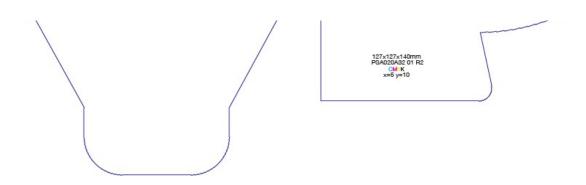
NADA # 121-473
Rev. 07/22

API Made in:



Approved by FDA under Exp:





PANACUR

fenbendazole granule

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FENBENDAZOLE (UNII: 621BVT9M36) (FENBENDAZOLE - UNII:621BVT9M36)	FENBENDAZOLE	222 mg in 1 g

	Packaging							
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
	NDC:57926-474-20	1 in 1 CARTON						
	L	454 g in 1 JAR						

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
NADA	NADA121473	01/05/1979				

Labeler - Merck Sharp & Dohme Corp. (001317601)

Revised: 11/2023 Merck Sharp & Dohme Corp.