# PANACUR- fenbendazole paste Schering Corporation

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panacur® (fenbendazole)

### Paste 10% (100 mg/g) Equine Dewormer

#### **DESCRIPTION:**

Panacur<sup>®</sup> (fenbendazole) Paste 10% contains the active anthelmintic, fenbendazole. The chemical name of fenbendazole is methyl 5-(phenylthio)-2-benzimidazole carbamate.

The chemical structure is:

Each gram of Panacur $^{\circledR}$  Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

### **ACTIONS:**

The antiparasitic action of Panacur<sup>®</sup> Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

#### INDICATIONS:

Panacur<sup>®</sup> Paste 10% is indicated for the treatment and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and for the control of arteritis caused by 4th stage larvae of *Strongylus vulgaris* in horses.

#### **PRECAUTIONS:**

Side effects associated with Panacur® Paste 10% could not be established in well-

controlled safety studies in horses with single doses as high as 454 mg/lb (1,000 mg/kg) and 15 consecutive daily doses of 22.7 mg/lb (50 mg/kg). Particularly with higher doses, the lethal action of fenbendazole may cause the release of antigens by the dying parasites. This phenomenon may result in either a local or systemic hypersensitivity reaction. As with any drug, these reactions should be treated symptomatically. Panacur® Paste 10% has been evaluated for safety in pregnant mares during all stages of gestation with doses as high as 11.4 mg/lb (25 mg/kg) and in stallions with doses as high as 11.4 mg/lb (25 mg/kg). No adverse effects on reproduction were detected. The recommended dose for control of 4th stage *Strongylus vulgaris* larvae, 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares.

#### **WARNINGS:**

NOT FOR USE IN HUMANS. KEEP OUT OF REACH OF CHILDREN. The Safety Data Sheet (SDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-800-211-3573. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS, or <a href="http://www.fda.gov/reportanimalae.">http://www.fda.gov/reportanimalae.</a>

OTHER WARNINGS: Do not use in horses intended for human consumption.

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.

### **DOSAGE:**

For foals and weanlings (less than 18 months of age) where ascarids are a common problem, the recommended dose is 4.6 mg/lb (10 mg/kg); one syringe will deworm a 550 lb horse.

For the control of large strongyles, small strongyles, and pinworms, the recommended dose is 2.3 mg/lb (5 mg/kg). One syringe will deworm a 1,100 lb horse.

For control of hypobiotic (encysted early 3rd stage), late 3rd stage, and 4th stage cyathostome larvae, as well as 4th stage *Strongylus vulgaris* larvae, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 550 lb body weight per day.

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. **DOSAGE:** Panacur<sup>®</sup> Paste 10% is administered orally at a rate of 2.3 mg/lb (5 mg/ kg) for the control of large strongyles, small strongyles, and pinworms. One syringe will deworm two 1,250 lb (568 kg) horses at a dose of 5 mg/kg. For foals and weanlings (less than 18 months of age) where ascarids are a common problem, the recommended dose is 4.6 mg/lb (10 mg/kg); one syringe will deworm a 1,250 lb horse.

For control of hypobiotic (encysted early 3rd stage), late 3rd stage, and 4<sup>th</sup> stage cyathostome larvae, as well as 4th stage *Strongylus vulgaris* larvae, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 1,250 lb body weight per day.

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.

#### **DIRECTIONS FOR USE:**

- 1. Determine the weight of the horse.
- 2. Remove syringe tip.
- 3. Turn the dial ring until the edge of the ring nearest the tip lines up with zero.
- 4. Depress plunger to advance paste to tip.
- 5. Set the dial ring at the graduation nearest the weight of the horse for the dosage rate of 5 mg/kg. For the dosage rate of 10 mg/kg, set the dial ring at two times (double) the horse's weight.
- 6. Horse's mouth should be free of food.
- 7. Insert nozzle of syringe through the interdental space and deposit the paste on the back of the tongue by depressing the plunger.

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

### **HOW SUPPLIED:**

Panacur® Paste 10% Equine Dewormer is supplied in 25 gram syringes.

Store at or below 25°C (77°F).

**HOW SUPPLIED:** Panacur<sup>®</sup> Paste 10% Equine Dewormer is supplied in 57 gram syringes, 5 per carton.

Store at or below 25°C (77°F).

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

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

Approved by FDA under NADA #120-648

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Rev. 8/21

# PRINCIPAL DISPLAY PANEL - 25 gram Syringe Carton

panacur<sup>®</sup> (fenbendazole)

Equine Dewormer

25 gram Paste 10% (100 mg/g)

MERCK Animal Health

# (fenbendazole)





# (fenbendazole)

# Equine **Dewormer**

25 gram Paste 10% (100 mg/g)







MERCK Animal Health

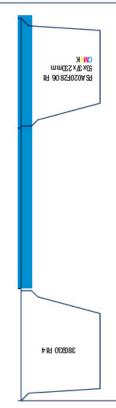
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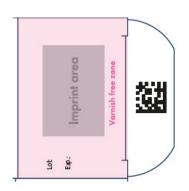
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Fenb endazole (active ingred.) ma in China. Formulated in France.

Approved by FDA under NADA 20-648

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### PRINCIPAL DISPLAY PANEL - 57 gram Syringe Carton

panacur<sup>®</sup> (fenbendazole)

**POWERPAC** 

**Equine Dewormer** 

Controls Encysted  $EL_3$  Small Strongyle Larvae

Controls both larval & adult parasites

MERCK Animal Health

# POVERPAC

# SAGRENOA" POWERPAC (fenbendazole)

Panacur\* (fenbendazole) is indicated for the control of:

- 4th stage S. vulgan's larvae
- Ascarids (Parascans equonum)
- Pinwoms (Oxyurisequi)
- small strongyle (cyathostome) larvae E<sup>3</sup> – euchz fed (hypobiotic) early 3rd stage
- eth stage mucosal cyatho stome laivae Tr³√r - encysted late 3rd stage and
- guisili strongyles (cyathostomes)
- S. equinus, S. vulgaris) Large strongyles (Strongy/lus edentatus,







Each gram of Panacur<sup>®</sup> Paste 10% contains 100 mg of tenbendazole and is flavored with artificial apple-cinnamon liquid.

ACTIONS:

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Inhibition or energy measurements and control of large strongles Protective Paris 10% is indicated for the treatment and control of large strongles Schongstlae advantates, S. aguituse, S. sudgests, encysted early and stage (hypotionic), late and stage and din stage opatinostome larvee, small stronglyke, philosome (Chyune equit, ascerates Pressesse aquirum), and control of attentite caused by 4th stage larvee of Stronglyke suggests in horses.

Stage larves of Strongydus vulgants in horses.

PRE CAUTIONES.
Side effects associated with Paracura Pastle 10% could not be established in well-controlled sately studies in horses with single doses as high as 454 mg/b (1,000 mg/kg) and 15 consecutive dealy doses of 227 mg/b (5) ng/kg). Particularly with higher doses, the latter action of tendenstance may cause he release of antigenis by the dying parasiles. This phenomenon may result in either a local or systemic higherentia bidly reaction. As with any drug, these reactions should be frested symplomatically.

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OTHER WARNINGS, to not use in horses intended for human consumption. Pransite resistance may develop in any developme, and has been recorded for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the entimately in the abeliance of pressite resistance. Recal examinations or other diagnosists tests and per sate management interrupt product is appropriate for the heart, prior to the use of any dewormer. For bothing the use of any dewormer, browling the use of a result ago count reduction tests and per sate of any development, and the sate of a result and proportion method. A deverse in a drugs effectiveness were time as calculated by feeding out reduction tests may indicate the development of resistance to the dewormer administered, Volumpersation management plan should be adjusted accordingly based on requisir monitoring.

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DIRECTIONS FOR USE

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2. Remove sytings (b).

3. Turn the did n'ight until the edge of the ring restrect the tip lines up with zero.

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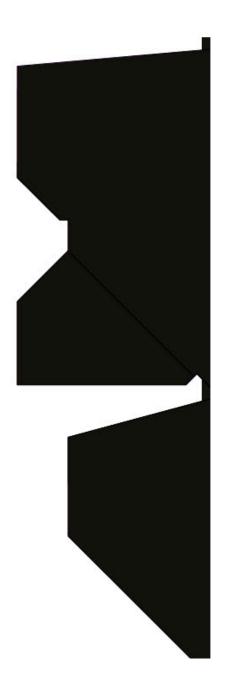
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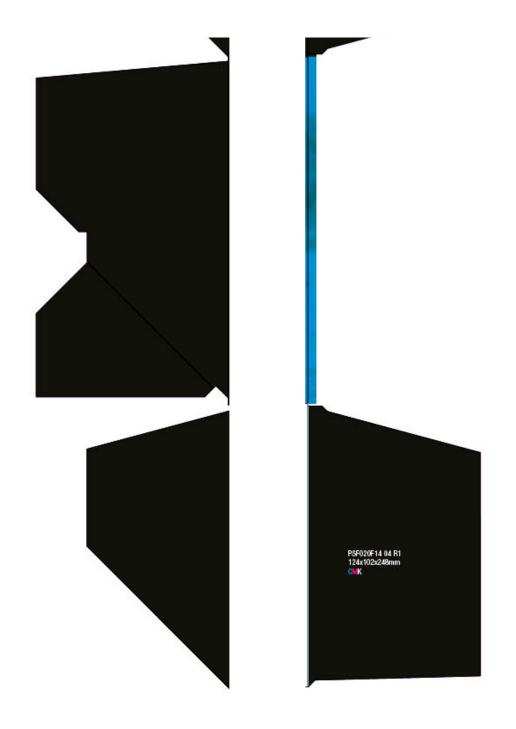
Approved by FDA under NACA # 120-648

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# **PANACUR**

fenbendazole paste

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-081
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
Fenbendazole (UNII: 621BVT9M36) (Fenbendazole - UNII:621BVT9M36)	Fenbendazole	100 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: HHT01ZNK31)			
Propylene Glycol (UNII: 6DC9Q167V3)			
Glycerin (UNII: PDC6A3C0OX)			
Sorbitol (UNII: 506T60A25R)			
Water (UNII: 059QF0KO0R)			
Sodium Hydroxide (UNII: 55X04QC32I)			
Methylparaben (UNII: A2I8C7HI9T)			
Propylparaben (UNII: Z8IX2SC1OH)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	APPLE, CINNAMON	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:57926-081-44	1 in 1 CARTON			
1		25 g in 1 SYRINGE, PLASTIC			

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing En Category Citation Date Date			
NADA	NADA120648	05/10/2010	

# **PANACUR**

fenbendazole paste

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Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:57926-082	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
Fenbendazole (UNII: 621BVT9M36) (Fenbendazole - UNII:621BVT9M36)	Fenbendazole	100 mg in 1 g	

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Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC10H)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	APPLE, CINNAMON	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:57926-082-48	1 in 1 CARTON			
1		57 g in 1 SYRINGE, PLASTIC			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
NADA	NADA120648	07/22/2011				

# Labeler - Schering Corporation (001317601)

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

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

Revised: 1/2022 Schering Corporation