PANACUR- fenbendazole paste
Schering Corporation

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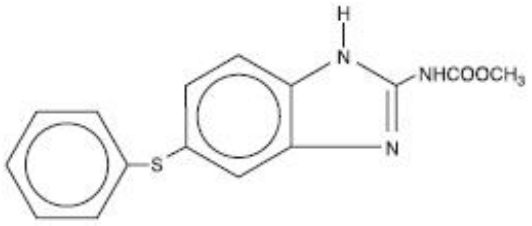
panacur®
(fenbendazole)

Paste 10% (100 mg/g) Equine Dewormer

DESCRIPTION

Panacur® (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® (fenbendazole) Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

ACTIONS

The antiparasitic action of Panacur® (fenbendazole) Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

INDICATIONS

Panacur® (fenbendazole) Paste 10% is indicated for the control of large strongyles *(Strongylus edentatus, S. equinus, S. vulgaris)*, encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, small strongyles, pinworms *(Oxyuris equi)*, ascarids *(Parascaris equorum)*, and arteritis caused by fourth stage larvae of *Strongylus vulgaris* in horses.

Panacur® (fenbendazole) Paste 10% is approved for use concomitantly with an approved form of trichlorfon. Trichlorfon is approved for the treatment of stomach bots *(Gasterophilus* spp.*)* in horses. Refer to the manufacturer's label for directions for use and cautions for trichlorfon.

PRECAUTIONS

Side effects associated with Panacur® (fenbendazole) 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 hypersensitive reaction. As with any drug, these reactions should be treated symptomatically.

Panacur® (fenbendazole) 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 reproductivity were detected. The recommended dose for control of 4th stage larvae of *Strongylus vulgaris*, 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares.

Internal Parasites

Regular deworming at intervals of six to eight weeks may be required due to the possibility of reinfection.

Migrating Tissue Parasites

In the case of 4th stage larvae of *Strongylus vulgaris*, treatment and retreatment should be based on the life cycle and the epidemiology. Treatment should be initiated in the spring and repeated in the fall after a six month interval.

Optimum Deworming Program for control of *S. vulgaris*

Optimum reduction of *S. vulgaris* infections is achieved by reducing the infectivity of the pastures. When horses are running on pasture, in temperate North America, maximum pasture infectivity occurs in October-December. If horses are removed from those pastures in January, pasture infectivity will decline to zero by July 1. Egg production of *S. vulgaris* is minimal from January through April, peaking in August and declining to minimal values in December.

Recommended Deworming Program

December 1, February 1, **April 1, June 1, August 1, **October 1**.

The two treatments that are in bold type are the recommended periods when the 5 day treatment regimen for the control of the migrating larvae of *S. vulgaris* should be performed.

**For other areas in the world, retreatment periods for the migrating larvae of *S. vulgaris* may be different; consult with your veterinarian.

CAUTIONS

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

When using Panacur® (fenbendazole) Paste 10% concomitantly with trichlorfon, refer to the manufacturer's labels for use and cautions for trichlorfon.

WARNING

Do not use in horses intended for human consumption

DOSAGE

Panacur® (fenbendazole) 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 a 1,100 lb horse. 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 control of encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, and fourth stage larvae of *Strongylus vulgaris*, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 550 Ibs body weight per day.

SEE PRECAUTIONS FOR RETREATMENT RECOMMENDATIONS.

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. Now set the dial ring at the graduation nearest the weight of the horse (do not underdose).
6. Horse's mouth must 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.

HOW SUPPLIED

Panacur® (fenbendazole) Paste 10% Equine Dewormer is supplied in 25 g syringes.

Store at or below 25°C (77°F).

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

Made in France

Distributed by:
Intervet Inc.
Millsboro, DE 19966

NADA # 120-648, Approved by FDA
For use in animals only.

PRINCIPAL DISPLAY PANEL - 100 mg/g Syringe Carton

intervet

panacur®
(fenbendazole)

Equine **Dewormer**

Equine
Dewormer
25 gram Paste 10%
(100 mg/g)

panacur®
(fenbendazole)
Equine **Dewormer**

Equine
Dewormer
25 gram Paste 10 %
(100 mg/g)

panacur®
(fenbendazole)
Equine **Dewormer**

Equine
Dewormer
25 gram Paste 10 %
(100 mg/g)

**For other areas in the world, retreatment periods for the migrating larvae of *S. vulgaris* may be different; consult with your veterinarian.

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

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DOSAGE:
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For control of encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, and fourth stage larvae of *Strongylus vulgaris*, the recommended dose is 4.6 mg/lb (10 mg/kg) daily for 5 consecutive days; administer one syringe for each 550 lbs body weight per day.

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3. Turn the dial ring until the edge of the ring nearest the tip lines up with zero.
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5. Now set the dial ring at the graduation nearest the weight of the horse (do not underdose).
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HOW SUPPLIED:
Panacur® (fenbendazole) Paste 10% Equine Dewormer is supplied in 25 g syringes.

Store at or below 25°C (77°F).

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

Made in France
Distributed by:
Intervet Inc.
Millsboro, DE 19966

NADA # 120-546, Approved by FDA
For use in animals only.

intervet

panacur®
(fenbendazole)
Paste 10% (100 mg/g) Equine Dewormer

DESCRIPTION:
Panacur® (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® (fenbendazole) Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

ACTIONS:
The antiparasitic action of Panacur® (fenbendazole) Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

INDICATIONS:
Panacur® (fenbendazole) Paste 10% is indicated for the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and arthritis caused by fourth stage larvae of *Strongylus vulgaris* in horses.

Panacur® (fenbendazole) Paste 10% is approved for use concomitantly with an approved form of trichlorfon. Trichlorfon is approved for the treatment of stomach bots (*Gasterophilus* spp.) in horses. Refer to the manufacturer's label for directions for use and cautions for trichlorfon.

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Internal Parasites: Regular deworming at intervals of six to eight weeks may be required due to the possibility of reinfection.

Migrating Tissue Parasites: In the case of 4th stage larvae of *Strongylus vulgaris*, treatment and retreatment should be based on the life cycle and the epidemiology. Treatment should be initiated in the spring and repeated in the fall after a six month interval.

Optimum Deworming Program for control of *S. vulgaris*: Optimum reduction of *S. vulgaris* infections is achieved by reducing the infectivity of the pastures. When horses are running on pasture, in temperate North America, maximum pasture infectivity occurs in October-December. If horses are removed from those pastures in January, pasture infectivity will decline to zero by July 1. Egg production of *S. vulgaris* is minimal from January through April, peaking in August and declining to minimal values in December.

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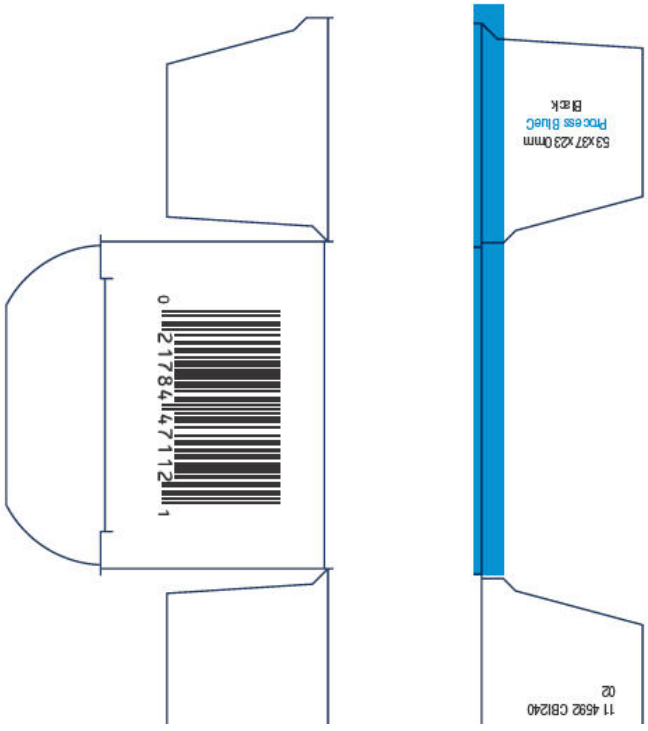
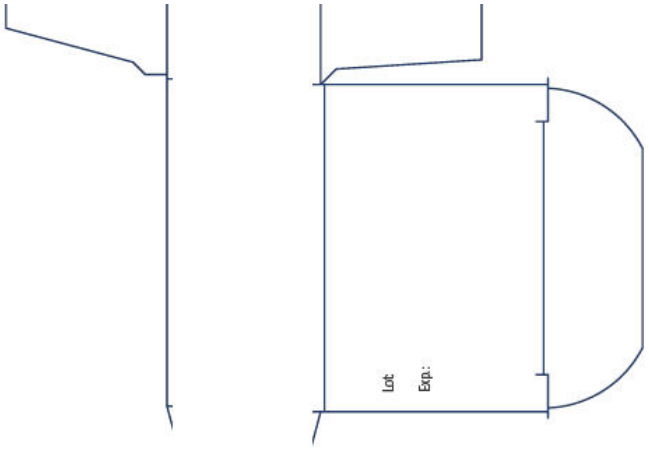
The two treatments that are in bold type are the recommended periods when the 5 day treatment regimen for the control of the migrating larvae of *S. vulgaris* should be performed.





PRINCIPAL DISPLAY PANEL - 100 mg/g Syringe Label

intervet

panacur®
(fenbendazole)

Equine **Dewormer** 57 gram Paste 10% (100 mg/g)

FOR USE IN ANIMALS ONLY.
Net Wt. 57 g (2.01 oz)

WARNING: DO NOT USE IN HORSES INTENDED FOR HUMAN CONSUMPTION.

DIRECTIONS:

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. Now set the dial ring at the graduation nearest the weight of the horse (do not underdose).
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.

The contents of one syringe will deworm two 1,250 lb (568 kg) horses at the standard dosage rate of 2.3 mg/lb (5 mg/kg). Refer to the carton for dosage and full directions for use and for treatment of ascarids, encysted early third stage (hypobiotic), late third stage and fourth stage cyathostome larvae and 4th stage larvae of Strongylus vulgaris as well as for concomitant use with trichlorfon.
CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT AND CONTROL OF PARASITISM.
Each syringe contains 5.7 g of fenbendazole.

Keep this and all medication out of the reach of children.
Store at or below 25°C (77°F).

Manufactured by: DPT Laboratories,
San Antonio, TX 78215

NADA # 120-648, Approved by FDA 129670

UPC CODE
021784047159

intervet

panacur®

(fenbendazole)

Equine **Dewormer** 57 gram Paste 10% (100 mg/g)

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Keep this and all medication out of the reach of children. Store at or below 25°C (77°F).
Made in France

Distributed by:
Intervet Inc., Millsboro, DE 19966
NADA # 120-648, Approved by FDA

048396 LPI240 02

intervet

Lot:

Exp.:

0 21784 04715 9

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	**Basis of Strength**	**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			

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

Marketing Information

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

PANACUR

fenbendazole paste

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Fenbendazole (UNII: 621BVT9M36) (Fenbendazole - UNII:621BVT9M36)	Fenbendazole	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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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: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	APPLE, CINNAMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	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	Business Operations
Intervet Production S.A.		771867553	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Intervet Mexico S.A. de C.V.		588215863	API MANUFACTURE

Revised: 6/2012 Schering Corporation