PANACUR- fenbendazole suspension Merck Sharp & Dohme Corp.

panacur® (fenbendazole) Dewormer

INDICATIONS: Beef and Dairy Cattle - 2.3 mg/lb (5 mg/kg) body weight 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* & *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*).

Beef Cattle Only – 4.6 mg/lb (10 mg/kg) body weight for the treatment and control of: **Stomach worms** (4th stage inhibited larvae): *Ostertagia ostertagi* (Type II Ostertagiasis); **Tapeworms:** *Moniezia benedeni.*

Do not use in dairy cattle at 10 mg/kg.

DIRECTIONS: Administer orally. In beef and dairy cattle, the recommended dose of 2.3 mg/lb (5 mg/kg) is achieved when 2.3 mL of the drug are given for each 100 lb of body weight. In beef cattle only, the recommended dose of 4.6 mg/lb (10 mg/kg) for treatment and control of Type II Ostertagiasis (4th stage inhibited larvae) or tapeworms is achieved when 4.6 mL of the drug is given for each 100 lb of body weight.

EXAMPLES:

Cattle Weight	Dose (2.3 mg/lb)	Dose 4.6 mg/lb	
100 lb	2.3 mL	4.6 mL	
200 lb	4.6 mL	9.2 mL	
300 lb	6.9 mL	13.8 mL	
400 lb	9.2 mL	18.4 mL	
500 lb	11.5 mL	23.0 mL	
1000 lb	23.0 mL	46.0 mL	
1500 lb	34.5 mL	69.0 mL	

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.

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 http://www.fda.gov/reportanimalae.

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.

Store at or below 25°C (77°F). Protect from freezing. Shake well before use.

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

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

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340358 R5

PRINCIPAL DISPLAY PANEL - 3,785 mL Bottle Label

panacur[®] (fenbendazole)

Dewormer for Beef & Dairy Cattle

Suspension 10% (100 mg/mL)

Withdrawal Periods and Residue Warnings: Milk taken from cows during treatment and for 48 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 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.

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

1 Gallon (3,785 mL)

LOT NUMBER:

EXPIRATION DATE:

MERCK Animal Health 359646 R3



for Beef & Dairy Cattle

Suspension 10% (100 mg/mL)

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imprint area









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Beef Cattle Only - 4.6 mg/lb (10 mg/kg) body weight for the treatment and control of: Stomach worms

Beef Cattle Only – 4.6 mg/lb (10 mg/kg) body weight for the treatment and control of: Stomach worms (4th stage inhibited larvae): Ostertagia ostertagi (Type II Ostertagiasis); Tapeworms: Moniezia benedeni. Do not use in dairy cattle at 10 mg/kg.

DIRECTIONS: Administer orally. In beef and dairy cattle, the recommended dose of 2.3 mg/lb (5 mg/kg) is achieved when 2.3 mL of the drug are given for each 100 lb of body weight. In beef cattle only, the recommended dose of 4.6 mg/lb (10 mg/kg) for treatment and control of Type II Ostertagiasis (4th stage inhibited larvae) or tapeworms is achieved when 4.6 mL of the drug is given for each 100 lb of body weight.

EXAMPLES:		
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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. 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 http://www.fda.gov/reportanimalae.
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Rev. 11/20







PANACUR

fenbendazole suspension

Product	Inform	ation
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Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:57926-086
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Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

water (UNII: 059QF0KO0R)

Ingredient Name	Strength
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
trisodium citrate dihydrate (UNII: B22547B95K)	
citric acid monohydrate (UNII: 2968PHW8QP)	

Packaging

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7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:57926-086-01	3785 mL in 1 BOTTLE			

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NADA	NADA128620	09/16/2009	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Intervet Production S.A.		771867553	ANALYSIS, MANUFACTURE

Establishment

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