VALBAZEN- albendazole suspension Zoetis Inc.

Valbazen[®] Suspension

Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4^{th} stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient:

Albendazole (Equivalent to 113.6 mg/mL)

11.36%

Indications:

Cattle and sheep: Valbazen is a broad-spectrum anthelmintic effective in the removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of *Ostertagia ostertagi*), intestinal worms, and lungworms as indicated below.

Goats: For the treatment of adult liver flukes in nonlactating goats.

Parasite	Cattle	Sheep	Goats
Adult Liver Flukes	Fasciola hepatica	Fasciola hepatica, Fascioloides magna	Fasciola hepatica
Heads and Segments of Tapeworms	•	Common Tapeworm (Moniezia	
Adult and 4th Stage Larvae of Stomach Worms	Brown Stomach Worm, including 4th stage inhibited larvae (Ostertagia ostertagi), Barber Pole Worm (Haemonchus contortus, H. placei), Small Stomach Worm (Trichostrongylus axei)	Brown Stomach Worm (Ostertagia circumcincta, Marshallagia marshalli), Barber Pole Worm (Haemonchus contortus), Small Stomach Worm (Trichostrongylus axei)	
Adult and 4th Stage Larvae of Intestinal Worms	Thread-necked Intestinal Worm (Nematodirus spathiger, N. helvetianus), Small Intestinal Worm (Cooperia punctata, C. oncophora)	Thread-necked Intestinal Worm (Nematodirus spathiger, N. filicollis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Oesophagostomum columbianum), Large-mouth Bowel Worm (Chabertia ovina)	
Adult Stages of Intestinal Worms	Hookworm (Bunostomum phlebotomum), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Oesophagostomum radiatum)		
Adult and 4th Stage Larvae of	Dictyocaulus viviparus		

Lungworms		
Adult and Larval		
Stages of	Dictyocaulus filaria	
Lungworms		

Dosage and Administration: Valbazen Suspension should be administered to cattle and goats at the recommended rate of 4 mL/100 lb of body weight (equivalent to 4.54 mg of albendazole/lb, 10 mg/kg) and to sheep at the recommended rate of 0.75 mL/25 lb of body weight (equivalent to 3.4 mg of albendazole/lb, 7.5 mg/kg). The following table indicates recommended dosing schedules.

Catt	le	Sheep		Goats		
Body Weight	Dosage	Body Weight	Dosage	Body Weight	Dosage	
250 lb	10 mL	25 lb	$0.75\mathrm{mL}$	25 lb	1 mL	
500 lb	20 mL	50 lb	1.5 mL	50 lb	2 mL	
750 lb	30 mL	75 lb	2.25 mL	75 lb	3 mL	
1000 lb	40 mL	100 lb	3.0 mL	100 lb	4 mL	
1250 lb	50 mL	200 lb	6.0 mL	125 lb	5 mL	
1500 lb	60 mL	300 lb	9.0 mL	150 lb	6 mL	

Cattle: 1 liter of Valbazen 11.36% Suspension will treat 50 animals weighing 500 lb.

Sheep: 1 liter of Valbazen 11.36% Suspension will treat 664 animals weighing 50 lb.

Goats: 1 liter of Valbazen 11.36% Suspension will treat 500 animals weighing 50 lb.

Valbazen 11.36% Suspension should be given orally using any type of standard dosing gun or dose syringe.

Important: Accurate estimates of the weight of the cattle, sheep, and goats to be treated are essential for most effective results with this product. Animals constantly exposed to internal parasites should be retreated as necessary.

Residue Warnings: Cattle must not be slaughtered within 27 days following last treatment. Sheep and Goats must not be slaughtered within 7 days following last treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in lactating does.

Precaution: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to ewes or does during the first 30 days of pregnancy or for 30 days after removal of rams or bucks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Keep This and All Medication Out of Reach of Children

Shake Well Before Using

For Use in Animals Only

Store at Controlled Room Temperature $20^{\circ} - 25^{\circ}C$ ($68^{\circ} - 77^{\circ}F$)

Protect From Freezing

Not for human use

Restricted Drug (California) - Use only as directed



Distributed by: Zoetis Inc. Kalamazoo, MI 49007 8784000 13945200 LOT

PRINCIPAL DISPLAY PANEL - 1 L/33.8 fl oz Bottle Label

VALBAZEN®

(albendazole)

EXP

Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient

Albendazole (equivalent to 113.6 mg/mL) 11.36%

1 L/33.8 fl oz (1 qt 1.8 fl oz)

NADA #110-048, Approved by FDA

8784000 13945100

zoetis



Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient

Albendazole (equivalent to 113.6 mg/mL)

1 L/33.8 fl oz (1 qt 1.8 fl oz)

8784000 13945100

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Broad-Spectrum DewormerOral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient:

Albendazole .

(Equivalent to 113.6 mg/mL)

Indications:

Cattle and sheep: Valbazen is a broad-spectrum anthelmintic effective in the removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms as indicated below.

Goats: For the treatment of adult liver flukes in nonlactating goats.

Parasite	Cattle	Sheep	Goats
Adult Liver Flukes	Fasciola hepatica	Fasciola hepatica, Fascioloides magna	Fasciola hepatica
Heads and Segments of Tapeworms	Moniezia benedeni, M. expansa	Common Tapeworm <i>(Moniezia expansa),</i> Fringed Tapeworm <i>(Thysanosoma actinioides)</i>	

Adult and 4th Stage Larvae of Stomach Worms	Brown Stomach Worm, including 4th stage inhibited larvae (Ostertagia ostertagii, Barber Pole Worm (Haemonchus contortus, H. placei), Small Stomach Worm (Trichostrongylus axei)	Brown Stomach Worm (Ostertagia circumcincta, Marshallagia marshalli), Barber Pole Worm (Haemonchus contortus), Small Stomach Worm (Trichostrongylus axei)	
Adult and 4th Stage Larvae of Intestinal Worms	Thread-necked Intestinal Worm (Nematodirus spathiger, N. helvetianus), Small Intestinal Worm (Cooperia punctata, C. oncophora)	Thread-necked Intestinal Worm (Nematodirus spathiger, N. filicollis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Oesophagostomum columbianum), Large-mouth Bowel Worm (Chabertia ovina)	
Adult Stages of Intestinal Worms	Hookworm (Bunostomum phlebotomum), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Oesophagostomum radiatum)		
Adult and 4th Stage Larvae of Lungworms	Dictyocaulus viviparus		
Adult and Larval Stages of Lungworms		Dictyocaulus filaria	

Dosage and Administration: Valbazen Suspension should be administered to cattle and goats at the recommended rate of 4 mL/100 lb of body weight (equivalent to 4.54 mg of albendazole/lb, 10 mg/kg) and to sheep at the recommended rate of 0.75 mL/25 lb of body weight (equivalent to 3.4 mg of albendazole/lb, 7.5 mg/kg). The following table indicates recommended dosing schedules.

Ca	ttle	Sheep		Goats	
Body Weight	Dosage	Body Weight	Dosage	Body Weight	Dosage
250 lb 500 lb 750 lb 1000 lb 1250 lb 1500 lb	10 mL 20 mL 30 mL 40 mL 50 mL 60 mL	25 lb 50 lb 75 lb 100 lb 200 lb 300 lb	0.75 mL 1.5 mL 2.25 mL 3.0 mL 6.0 mL 9.0 mL	25 lb 50 lb 75 lb 100 lb 125 lb 150 lb	1 mL 2 mL 3 mL 4 mL 5 mL 6 mL

Cattle: 1 liter of Valbazen 11.36% Suspension will treat 50 animals weighing 500 lb. Sheep: 1 liter of Valbazen 11.36% Suspension will treat 664 animals weighing 50 lb. Goats: 1 liter of Valbazen 11.36% Suspension will treat 500 animals weighing 50 lb. Valbazen 11.36% Suspension should be given orally using any type of standard dosing gun or dose syringe.

Important: Accurate estimates of the weight of the cattle, sheep, and goats to be treated are essential for most effective results with this product. Animals constantly exposed to internal parasites should be retreated as necessary.

Residue Warnings: Cattle must not be slaughtered within 27 days following last treatment. Sheep and Goats must not be slaughtered within 7 days following last treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in lactating does. Precaution: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to ewes or does during the first 30 days of pregnancy or for 30 days after removal of rams or bucks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Keep This and All Medication Out of Reach of Children Shake Well Before Using

For Use in Animals Only

Store at Controlled Room Temperature 20° - 25°C (68° - 77°F)

Protect From Freezing Not for human use

Restricted Drug (California) - Use only as directed



OBSERVE LABEL

zoetis

Distributed by: Zoetis Inc. Kalamazoo, MI 49007

8784000



LOT **EXP**

PRINCIPAL DISPLAY PANEL - 5 L/169 fl oz Bottle Label

VALBAZEN®

(albendazole)

Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient

Albendazole (equivalent to 113.6 mg/mL) 11.36%

5 L/169 fl oz (1 gal 1 qt 9 fl oz)

NADA #110-048, Approved by FDA

8785000 13945600

zoetis



(albendazole)

Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient

5 L/169 fl oz (1 gal 1 qt 9 fl oz)

NADA #110-048, Approved by FDA

8785000 13945600

zoetis



Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for

Indications:

removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in

nonlactating goats Active Ingredient:

Albendazole 11.36%

(Equivalent to 113.6 mg/mL)

Cattle and sheep: Valbazen is a broad-spectrum anthelmintic effective in the removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms as indicated below.

Goats: For the treatment of adult liver flukes in nonlactating goats.

Parasite	Cattle	Sheep	Goats
Adult Liver Flukes	Fasciola hepatica	Fasciola hepatica, Fascioloides magna	Fasciola hepatica
Heads and Segments of Tapeworms	Moniezia benedeni, M. expansa	Common Tapeworm (Moniezia expansa), Fringed Tapeworm (Thysanosoma actinioides)	
Adult and 4th Stage Larvae of Stomach Worms	Brown Stomach Worm, including 4th stage inhibited larvae (Ostertagia ostertagi), Barber Pole Worm (Haemonchus contortus, H. placei), Small Stomach Worm (Trichostrongylus axei)	Brown Stomach Worm (Ostertagia circumcincta, Marshallagia marshalli), Barber Pole Worm (Haemonchus contortus), Small Stomach Worm (Trichostrongylus axei)	
Adult and 4th Stage Larvae of Intestinal Worms	Thread-necked Intestinal Worm (Nematodirus spathiger, N. helvetianus), Small Intestinal Worm (Cooperia punctata, C. oncophora)	Thread-necked Intestinal Worm (Nematodirus spathiger, N. filicollis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Ossophagostomum columbianum), Large-mouth Bowel Worm (Chabertia ovina)	
Adult Stages of Intestinal Worms	Hookworm (Bunostomum phlebotomum), Bankrupt Worm (Trichostrongylus colubriformis), Nodular Worm (Oesophagostomum radiatum)		
Adult and 4th Stage Larvae of Lungworms	Dictyocaulus viviparus		
Adult and Larval Stages of Lungworms		Dictyoca ulus filaria	

Dosage and Administration: Valbazen Suspension should be administered to cattle and goats at the recommended rate of 4 mL/100 lb of body weight (equivalent to 4.54 mg of albendazole/lb, 10 mg/kg) and to sheep at the recommended rate of 0.75 mL/25 lb of body weight (equivalent to 3.4 mg of albendazole/lb, 7.5 mg/kg). The following table indicates recommended dosing schedules.

Catt	attle Sheep		Sneep		is .
Body Weight	Dosage	Body Weight	Dosage	Body Weight	Desage
250 lb 500 lb	10 mL 20 mL	25 lb 50 lb	0.75 mL 1.5 mL	25 lb 50 lb	1 mL 2 mL
750 lb	30 mL	75 lb	2.25 mL	75 lb	3 mL
1000 lb	40 mL	100 lb	3.0 mL	100 lb	4 mL
1250 lb	50 mL	200 lb	6.0 mL	125 lb	5 mL
1500 lb	60 mL	300 lb	9.0 mL	150 lb	6 mL

Cattle: 5 liters of Valbazen 11.36% Suspension will treat 250 animals weighing 500 lb. Sheep: 5 liters of Valbazen 11.36% Suspension will treat 3320 animals weighing 50 lb. Goats: 5 liters of Valbazen 11.36% Suspension will treat 2500 animals weighing 50 lb.

Valbazen 11.36% Suspension should be given orally using any type of standard dosing gun or dose syringe.

Important: Accurate estimates of the weight of the cattle, sheep, and goats to be treated are essential for most effective results with this product. Animals constantly exposed to internal parasites should be retreated as necessary.

Residue Warnings: Cattle must not be slaughtered within 27 days following last treatment. Sheep and Goats must not be slaughtered within 7 days following last treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in lactating does.

Precaution: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to ewes or does during the first 30 days of pregnancy or for 30 days after removal of rams or bucks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Keep This and All Medication Out of Reach of Children

Shake Well Before Using

For Use in Animals Only

Store at Controlled Room Temperature 20° - 25°C (68° - 77°F) Protect From Freezing

Not for human use

Restricted Drug (California) - Use only as directed

zoetis Distributed by:

Zoetis Inc. Kalamazoo, MI 49007

8785000 13945500



PRINCIPAL DISPLAY PANEL - 500 mL/16.9 fl oz Bottle Label

VALBAZEN®

(albendazole)

Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Active Ingredient:

Albendazole

(Equivalent to 113.6 mg/mL) 11.36%

500 mL/16.9 fl oz (1 pt 1 fl oz)

NADA #110-048, Approved by FDA

zoetis



Broad-Spectrum Dewormer

Oral Suspension for Use in Cattle, Sheep, and Goats for removal and control of liver flukes, tapeworms, stomach worms (including 4th stage inhibited larvae of Ostertagia ostertagi), intestinal worms, and lungworms in cattle and sheep and for the treatment of adult liver flukes in nonlactating goats

Activ	e I	ngre	dient:	

Albendazole (Equivalent to 113.6 mg/mL)

Precaution: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to ewes or does during the first 30 days of pregnancy or for 30 days after removal of rams or bucks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

500 mL/16.9 fl oz (1 pt 1 fl oz)

NADA #110-048, Approved by FDA

zoetis

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Dosage and Administration: Valbazen Suspension should be administered to cattle and goats at the recommended rate of 4 mU/100 lb of body weight (equivalent to 4,54 mg of albendazole/lb, 10 mg/kg) and to sheep at the recommended rate of 0.75 mL/25 lb of body weight (equivalent to 3,4 mg of albendazole/lb, 7,5 mg/kg). The following table indicates recommended dosing schedules.

2ml 2ml 3ml 5ml

25 lb 50 lb 75 lb 200 lb 300 lb

Body Weight

VA Ad

ates of the weight of the cattle, sheep, and goats to be treated are essential for most effective results constantly exposed to internal parasites should be retreated as necessary. Zoetis Inc. Kalamazoo, MI 49007 Distributed by: zoetis /albazen 11.36% Suspension should be given orally using any type of standard dosing gun or dose syringe. Cattle: 500 mL of Valbazen 11.36% Suspension will treat 25 animals weighing 500 lb. Sheep: 500 mL of Valbazen 11.36% Suspension will treat 332 animals weighing 50 lb. Goats: 500 mL of Valbazen 11.36% Suspension will treat 250 animals weighing 50 lb.

Store at Controlled Room Temperature 20° - 25°C (68° - 77°F) Restricted Drug (California) - Use only as directed Shake Well Before Using For Use in Animals Only Protect From Freezing Not for human use

Keep This and All Medication Out of Reach of Children

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ndications:

Cattle and sheep: Valbazen is a broad-spectrum anthelmintic effective in the removal and control of liver flukes, tape

Fasci	Fasciola hepatica, Fascioloides magna	Fasciola hepatica	Adult Liver Flukes
Goats	Sheep	Cattle	Parasite

dult I war Flukes Fascinia hanatica Fascinia hanatica Fascinia		
radional inchange	Fasciola hepatica, Fascioloides magna	Fascio
eads and Segments Moniezia benedeni, M. expansa Common Tapeworm (Mo	Common Tapeworm (Moniezia expansa), Fringed Tapeworm (Thysanosoma actinioides)	
duit and 4th Stage Brown Stomach Worm, including sirvae of Stomach (Ostertagia sirvae) Orms: Worm (Haemonchus contortus, H. placel), Small Stomach Worm (Trichostrongylus axei)	Brown Stomach Worm (Ostertagia ofrcumcincta, Marshallagia marshall), Barher Pole Worm (Haemonchus contortus), Small Stomach Worm (Trichostrongylus axei)	
dult and 4th Stage Thread-necked Intestinal Worm Spathiger, N. filcolis), C. Vorms Vorm	Thread-necked Intestinal Worm (Nematodirus spathiger, N. filicoliis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostrongylus colubriformis), Nodular (Trichostrongylus colubriformis), Nodular (Worm (Oesophagostomum columbianum), Large-mouth Bowel Worm (Chabertia ovina)	
dult Stages of Hookworm (Bunostomum phiebotomum), Bankrupt Worm, [Trichostrongylus colibriformis], Nodular Worm (Desophagostomum radiatum)		
dult and 4th Stage Dictyocaulus viviparus arvae of Lungworms		
dult and Larval tages of Lungworms	us filaria	
Residue Warnings: Cattle must not be slaughtered within 27 days following last treatment. Sheep and Goats must slaughtered within 7 days following last treatment. Because a withdrawal time in milk has not been established, use in famale dairy cattle of breeding and. Do not use in factating does.	ollowing last treatment. Sheep and Goodrawal time in milk has not been estab hes	oats mu blished,

VALBAZEN

albendazole suspension

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:54771-8783

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
albendazole (UNII: F4216019LN) (albendazole - UNII:F4216019LN)	albendazole	113.6 mg in 1 mL

Inactive Ingredients Ingredient Name Strength CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) GLYCERIN (UNII: PDC6A3C0OX) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) POLYSORBATE 80 (UNII: 6OZP39ZG8H) BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:54771-8783-1	500 mL in 1 BOTTLE							
2	NDC:54771-8783-2	1000 mL in 1 BOTTLE							
3	NDC:54771-8783-3	5000 mL in 1 BOTTLE							

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
NADA	NADA110048	06/13/1989						

Labeler - Zoetis Inc. (828851555)

Establishment									
Name	Address	ID/FEI	Business Operations						
Zoetis LLC		039055157	MANUFACTURE						

Establishment							
Name	Address	ID/FEI	Business Operations				
UQUIFA Mexico, S.A. DE C.V.		810105874	API MANUFACTURE				

Revised: 5/2014 Zoetis Inc.