VALBAZEN- albendazole suspension Zoetis Inc.

VALBAZEN®

VALBAZEN[®] (albendazole oral suspension)

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	11.36%
(Equivalent to 113.6 mg/mL)	

Approved by FDA under NADA # 110-048

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			Fasciola
Flukes	Fasciola hepatica	Fasciola hepatica, Fascioloides magna	hepatica
Heads and	Moniezia benedeni, M. expansa	Common Tapeworm (Moniezia expansa),	
Segments		Fringed Tapeworm (Thysanosoma actinioides)	
of			
Tapeworms			
Adult and	Brown Stomach Worm, including	Brown Stomach Worm (Ostertagia circumcincta,	
4th Stage	4th stage inhibited larvae	<i>Marshallagia marshalli)</i> , Barber Pole Worm	
Larvae of		(Haemonchus contortus), Small Stomach Worm	
	•	(Trichostrongylus axei)	
Worms	<i>placei)</i> , Small Stomach Worm		
	(Trichostrongylus axei)		
Adult and	Thread-necked Intestinal Worm	Thread-necked Intestinal Worm (Nematodirus	
0	(Nematodirus spathiger, N.	spathiger, N. filicollis), Cooper's Worm	
		(Cooperia oncophora), Bankrupt Worm	
	(Cooperia punctata, C. oncophora)	(Trichostrongylus colubriformis), Nodular Worm	
Worms		(Oesophagostomum columbianum), Large-mouth	
		Bowel Worm (Chabertia ovina)	
	Hookworm (Bunostomum		
	phlebotomum), Bankrupt Worm		
	(Trichostrongylus colubriformis),		
Worms	Nodular Worm		

	(Oesophagostomum radiatum)		
Adult and	Dictyocaulus viviparus		I
4th Stage			I
Larvae of			I
Lungworms			I
Adult and		Dictyocaulus filaria	I
Larval			I
Stages of			I
Lungworms	3		

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. 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.

Cat	tle	She	ер	Goats								
Body Weig	htDosage	Body Weig	htDosage	Body Weigl	ntDosage							
250 lb	10 mL	25 lb	0.75 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.

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/flock, 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.

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



Distributed by: Zoetis Inc. Kalamazoo, MI 49007

40029176

LOT EXP

PRINCIPAL DISPLAY PANEL - 1 L/33.8 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%

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

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Albendazole (equivalent to 113.6 mg/mL)

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Active Ingredient:

Albendazole	11.36%
(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 (Moniezia expansa), Fringed Tapeworm (Thysanosoma actinioides)	

Adult and 4th Stage Larvae of Stomach Worms	Brown Stomach Worm, includ inhibited larvae (Ostertagia os Worm (Haemonchus contortu: Stomach Worm (Trichostrong)	<i>tertagi),</i> Barber Pole s, H. placei), Small	Brown Stomach Worm (<i>Ostertagia</i> marshalli), Barber Pole Worm (Hae Stomach Worm (<i>Trichostrongylus a</i>	monchus contortus), Small	
Adult and 4th Stage Larvae of Intestinal Worms	Thread-necked Intestinal Wor spathiger, N. helvetianus), Sm (Cooperia punctata, C. oncoph	all Intestinal Worm	Thread-necked Intestinal Worm (N Cooper's Worm (Cooperia oncopho (Trichostrongylus colubriformis), N columbianum), Large-mouth Bowel	No. 11	
Adult Stages of Intestinal Worms	Hookworm (Bunostomum phle Worm (Trichostrongylus colub Worm (Oesophagostomum rad	niformis), Nodular			
Adult and 4th Stage Larvae of Lungworms	Dictyocaulus viviparus				
Adult and Larval Stages of Lungworms			Dictyocaulus filaria		
	and to sheep at the recommende		tle and goats at the recommended ra of body weight (equivalent to 3.4 mg Sheep		The following table indicate
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
heep: 1 liter of Valbazen Roats: 1 liter of Valbazen albazen 11.36% Suspens un or dose syringe. mportant: Accurate estin reated are essential for n xposed to internal paras Residue Warnings: C treatment. Sheep and last treatment. Becau	11.36% Suspension will treat 50 ar 11.36% Suspension will treat 664 11.36% Suspension will treat 500 a ion should be given orally using a nates of the weight of the cattle, sl nost effective results with this pro ites should be retreated as necess attle must not be slaughtered with I Goats must not be slaughtered with I Goats must not be slaughtered with I se a withdrawal time in milk has dairy cattle of breeding age. Do no	animals weighing 50 l Inimals weighing 50 lt ny type of standard do heep, and goats to be duct. Animals constar sary. in 27 days following la rithin 7 days following not been established.	b. b. for 45 days after removal of 30 days of pregnancy or for veterinarian for assistance Keep This and All Medicati Shake Well Before Using or Use in Animals Only Store at Controlled Room T Protect From Freezing Not for human use Restricted Drug (California	ter to female cattle during first bulls. Do not administer to ew 30 days after removal of rams in the diagnosis, treatment, an on Out of Reach of Children emperature 20° – 25°C (68° – 7 TAKE) - Use only as directed	res or does during the first or bucks. Consult your d control of parasitism. 7°F)
Cells			PPU: UPC		

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



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

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

NADA #110-048, Approved by FDA

8785000 13945600

<mark>zoetis</mark>



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 (<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 ostertagi), Barber Pole Worm (Haemonchus contortus, H. placei), Small Stomach Worm (Trichostrongylus axei)	Brown Stomach Worm (<i>Ostertagia circumcincta, Marshallagia</i> marshalli), Barber Pole Worm (<i>Haemonchus contortus</i>), Small Stomach Worm (<i>Trichostrongylus axei</i>)	
Adult and 4th Stage Larvae of Intestinal Worms	Thread-necked Intestinal Worm (<i>Nematodirus</i> spathiger, N. heivetianus), Small Intestinal Worm (Cooperia punctata, C. oncophora)	Thread-necked Intestinal Worm (Nematodirus spathiger, N. filicollis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostr ongylus colubriformis), Nodular Worm (Oesophagostonum 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.

Cattle		Sheep		Goa	ts
Body Weight	Dosage	Body Weight	Dosage	Body Weight	Desage
250 lb	10 mL	25 lb	0.75 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
Important: Accurate estimates of with this product. Animals const Residue Warnings: Cattle not be slaughtered within established, do not use in Precaution: Do not administer to	ould be given orally using a ould be given orally using a antly exposed to internal pri must not be slaughtered wi 7 days following last treatm female dairy cattle of breed of female cattle during first 4 of gthe first 30 days of pregn e diagnosis, treatment, and ut of Reach of Children	my type of standard dosing gun or heep, and goats to be treated are arasites should be retreated as ne thin 27 days following last treatme tent. Because a withdrawal time i ling age. Do not use in lactating d 5 days of pregnancy or for 45 day ancy or for 30 days after removal control of parasitism.	essential for most effective acessary. ent. Sheep and Goats mus n milk has not been oes. s after removal of bulls. Do	t o not	OBSERVE LABEL DIRECTIONS FPO:UPC
•	erature 20° – 25°C (66° – 77	°F) zoetis			
rotect From Freezing		Distributed by:	070500		
lot for human use		Zoetis Inc.	Zoetis Inc. 8785000		
Restricted Drug (California) - Us	se only as directed	Kalamazoo, MI 4900	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

Active Ingredient:

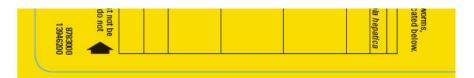
Albendazole	1																					1	1	.36	5%	6
(Equivalent t	0	1	1:	3	6	r	n	g	1	n	1	L)														

500 mL/16.9 fl oz (1 pt 1 fl oz) NADA #110-048, Approved by FDA

zoetis

Precaution: Do not administer rams or bucks. Consult)	Residue Warnings	Adult and Larval Stages of Lungworms	Adult and 4th Stage Larvae of Lungworms	Adult Stages of Intestinal Worms	Aduit and 4th Stage Larvae of Intestinal Worms	Aduit and 4th Stage Larvae of Stomach Worms	Heads and Segments of Tapeworms	Adult Liver Flukes	Parasite	Cattle and sheep: Valba Stomach worms (includi Goats: For the treatmen
use in temale dairy cattle of thereding age, of durations, so character a twistion suite in temale dairy cattle of thereding age. Do not use in lactating does aution: Do not administer to female cattle during first 45 days of pregnan Do not administer to evere of does during the first 30 days of pregnanc or bucks. Consult your veterinarian for assistance in the diagnosis, tree	:: Cattle must not be slaughtered with of days following last treatment Rec		Dictyocaulus viviparus	Hookworm (Bunostamum phlebotamum), Bankrupt Worm (Trichostrongylus colubritormis), Nodular Worm (Desophagostamum radiatum)	Thread-necked Intestinal Worm (Nematodirus spathiger, (Netretianus), Small Intestinal Worm (Cooperia punctata, C. oncophora)	Brown Stomach Worm, including 4th stage inhibited larvae (<i>Ostertagia ostertagi</i>), Barber Pole Worm (<i>Haemonchus contortus</i> , <i>H. placeit</i> , Small Stomach Worm (<i>Trichostrongylus axei</i>)	Moniezia benedeni, M. expansa	Fasciola hepatica	Cattle	Innucuous. Cattle and sheep: Valba zen is a broad-spectrum antheimintic effe stomach worms (including 4th stage inhibited larvae of <i>Ostertagia</i> Goats: For the treatment of adult liver flukes in nonlactating goats
Precartion: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Do not administer to eves 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.	Residue Warnings: Cattle must not be slaughtered within 27 days following last treatment. Sheep and Goats mus sloughtered within 7 days following bettreatmoot Receives a withdrawed time in milk has not been astablished.	Dictyocaulus filaria			Thread-necked Intestinal Worm (Nematodirus spathiger, N. filcoliis), Cooper's Worm (Cooperia oncophora), Bankrupt Worm (Trichostrongylus colubriformis), Nodular (Trichostrongylus colubriformis), Nodular Worm (Oscophagostornum columbianum), Large-mouth Bowel Worm (Chabertia ovina)	Brown Stomach Worm <i>(Ostertagia</i> oircumcincta, Marshallegia marshalil), Barber Pole Worm <i>(Haemonchus contortus),</i> Small Stomach Worm <i>(Trichostrongylus axei)</i>	Common Tapeworm (Moniezia expansa), Fringed Tapeworm (Thysanosoma actinioides)	Fasciola hepatica, Fascioloides magna	Sheep	Cattle and sheep. Valbazen is a broad-spectrum anthelminitic effective in the removal and control of liver flukes, tapev stomach worms (including 4th stage inhibited larvae of <i>Ostertagia ostertagit</i>), intestinal worms, and lungworms as indic Goats. For the treatment of adult liver flukes in nonlactating goats.
)ats mu							Fascio	Goats	as, tape s as indi

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. 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. Dosage Zoetis Inc. Kalamazoo, MI 49007 Distributed by: zoetis Goats 0 albazen 11.36% Suspension should be given orally using any type of standard dosing gun or dose syringe. Body Weight 25 10 125 10 125 10 125 10 125 10 *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 322 animals weighing 50 lb. *Goats*: 500 mL of Valbazen 11.36% Suspension will treat 250 animals weighing 50 lb. 0 0.75 mL 1.5 mL 2.25 mL 3.0 mL 6.0 mL 9.0 mL Dosage -N Sheep 00 Store at Controlled Room Temperature 20° – 25°C (68° – 77°F) Body Weight 25 b 50 b 200 b 200 b **Reach of Children** 0 Restricted Drug (California) - Use only as directed with this product Animals constantly keep This and All Medication Out of Dosage mportant: Accurate estim Shake Well Before Using Cattle For Use in Animals Only Protect From Freezing Not for human use Body Weight 250 b 500 b 750 b 1250 b 1250 b 1250 b TO TO



alben	dazole suspensio	n				
Pro	duct Informatio	on				
Prod	duct Type	OTC ANIMAL DRUG	Ite m Co	de (Source)	NDO	C:54771-8783
Rou	te of Administrati	on ORAL				
Acti	ive Ingredient/A	Active Moiety				
		Ingredient Name		Basis of Stren	ngth	Strength
albe	ndazole (UNII: F421	6019LN) (albendazole - UNII:F4216019)LN)	albendazole		113.6 mg in 1 mL
GLY POT	CERIN (UNII: PDC6.	E (UNII: 1VPU26JZZ4)			(Strength 5 mg in 1 mL
	ZOIC ACID (UNII: 8					
Pac	kaging					
#	Item Code	Package Description	Marketing	g Start Date	Mark	eting End Date
	DC:54771-8783-1	500 mL in 1 BOTTLE				
_	DC:54771-8783-2 DC:54771-8783-3	1000 mL in 1 BOTTLE				
	rketing Info	rmation Application Number or Monogi	anh Citatian	Marketing Start Da	to M	arketing End Dat
Mar	Kenne Galegory	Application Number of Monogr	apir Chauon	marketing Start Da		ai keung Enu Dau

Labeler - Zoetis Inc. (828851555)

Revised: 6/2020