

NADA Number: 110-048

Trade Name	Valbazen®
Sponsor	Zoetis Inc.
Ingredients	Albendazole
Species	Cattle (Cattle, dairy, excluding female breeding age animals) Cattle (Cattle, beef) Cattle (Cattle, restricted during pregnancy) GOATS (NON-LACTATING) SHEEP (DOMESTIC) (Sheep, restricted during pregnancy)
Routes of Administration	ORAL
Dosage Form	LIQUID (SUSPENSION)
Dispensing Status	OTC
Exclusivity	Seven year period of marketing exclusivity granted for the use of albendazole in the treatment of adult liver fluke (<i>Fasciola hepatica</i>) in nonlactating goats for (1/24/2015).
Specifications	The product contains 11.36 percent albendazole.
Dosage Amount, Indications & Limitations	<p>Cattle</p> <p>Dosage: 4 mL/100 lb of body weight (equivalent to 4.54 mg of albendazole/lb, 10 mg/kg). Administer as a single oral dose using dosing gun or dosing syringe.</p> <p>Indications: For removal and control of the following internal parasites of cattle: adult liver flukes (<i>Fasciola hepatica</i>), heads and segments of tapeworms (<i>Moniezia benedeni</i>, <i>M. expansa</i>); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (<i>Ostertagia ostertagi</i>), barberpole worm (<i>Haemonchus contortus</i>, <i>H. placei</i>), small stomach worm (<i>Trichostrongylus axei</i>)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (<i>Nematodirus spathiger</i>, <i>N. helvetianus</i>), small intestinal worm (<i>Cooperia punctata</i> and <i>C. oncophora</i>)); adult stages of intestinal worms (hookworm (<i>Bunostomum phlebotomum</i>) bankrupt worm (<i>Trichostrongylus colubriformis</i>), nodular worm (<i>Oesophagostomum radiatum</i>)); adult and 4th stage larvae of lungworms (<i>Dictyocaulus viviparus</i>).</p> <p>Limitations: Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls.</p> <p>Sheep</p> <p>Dosage: 0.75 mL/25 lb of body weight (equivalent to 3.4 mg of albendazole/lb, 7.5 mg/kg) as a single oral dose using dosing gun or dosing syringe.</p> <p>Indications: For removal and control of the following internal parasites of sheep: Adult liver flukes (<i>Fasciola hepatica</i>, <i>Fascioloides magna</i>); heads and segments of common tapeworms (<i>Moniezia expansa</i>) and fringed tapeworm (<i>Thysanosoma actinoides</i>); adult and fourth stage larvae of stomach worms (brown stomach worm (<i>Ostertagia circumcincta</i> and <i>Marshallagia marshalli</i>), barberpole worm (<i>Haemonchus contortus</i>), small stomach worm (<i>Trichostrongylus axei</i>)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (<i>Nematodirus spathiger</i> and <i>N. filicollis</i>), Cooper's worm (<i>Cooperia oncophora</i>), bankrupt worm (<i>Trichostrongylus colubriformis</i>), nodular worm (<i>Oesophagostomum columbianum</i>), and large-mouth bowel worm (<i>Chabertia ovina</i>)); adult and larval stages of lungworms (<i>Dictyocaulus filaria</i>).</p> <p>Limitations: Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams.</p> <p>Goats (non-lactating)</p> <p>Dosage: 4 mL/100 lb of body weight (equivalent to 4.54 mg of albendazole/lb, 10 mg/kg). Administer as a single oral dose using dosing gun or dosing syringe.</p> <p>Indications: For the treatment of adult liver flukes (<i>Fasciola hepatica</i>) in nonlactating goats.</p> <p>Limitations: Do not administer to does during first 30 days of pregnancy or for 30 days after removal of bucks. Do not use in lactating does.</p>

Tolerances

Albendazole: Tolerances are established for residues of albendazole in uncooked edible tissues as follows:

- a. In cattle: the tolerance for the 2-aminosulfone metabolite (marker residue) in liver (target tissue) is 0.2 part per million and in muscle 0.05 part per million.
- b. In sheep: the tolerance for the 2-aminosulfone metabolite (marker residue) in liver (target tissue) is 0.25 part per million and in muscle of 0.05 part per million.