

NADA Number: 096-298	
Trade Name	Avatec® Bovatec® Type A Medicated Article Bovatec® 68 Type A Medicated Article Bovatec® Liquid 20 (liquid Type A Article) Bovatec® Premix
Sponsor	Alpharma, Inc.
Ingredients	Lasalocid
Species	Domestic rabbit, young Cattle, fed in confinement for slaughter Chukar partridges, up to 8 weeks of age Turkey, growing Chicken, fryers Cattle, dairy, heifers on pasture Cattle, calves, excluding veal calves Sheep, confinement Cattle, beef, on pasture Chicken, broilers
Routes of Administration	Per Os
Dose Form	Medicated feed
Drug Form	Type A Medicated Article
Dispensing Status	OTC
Patent Number	3715372 4594354 RE29244
Exclusivity	Granted for the use of a generic free-choice high phosphorus loose mineral feed containing 1088 grams of lasalocid per ton feed in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). For use in growing turkeys.
	558.311 Lasalocid.  Specifications: A minimum of 90 percent of lasalocid activity is derived from lasalocid A. Type A medicated articles: 15, 20, 33.1, and 50 percent for cattle feeds. Type A medicated articles: 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20 or 50 percent for chicken feed Type A medicated articles: 20 percent for chukar partridge feed Type A medicated articles: 20 percent for growing turkey feed Type A medicated articles: 20 percent for rabbit feed.  Conditions of use:  Chickens (broilers or fryers)

Amount: 68 (0.0075 percent) to 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*

Limitations: For broiler or fryer chickens only. Feed continuously as the sole ration.

Partridges (chukar)

Amount: 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For prevention of coccidiosis caused by *Eimeria legionensis*

Limitations: For chukar partridges only. Feed continuously as sole ration up to 8 weeks of age.

Turkeys (growing)

Amount: 68 (0.0075 percent) to 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For the prevention of coccidiosis caused by *E. meleagritidis*, *E. gallopavonis*, and *E. adenoeides*.

Limitations: For growing turkeys only. Feed continuously as the sole ration.

Cattle (fed confinement for slaughter)

Amount: 10 (0.0011 percent) to 30 (0.0033 percent) grams Lasalocid sodium per ton of feed.

Indications For improved feed efficiency

Limitations: In Type C feeds. Feed continuously daily in complete feed to provide not less than 100 milligrams nor more than 360 milligrams of lasalocid sodium activity per head per day. Feeding undiluted, mixing errors, or inadequate mixing may result in excess lasolacid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasolacid as ingestion may be fatal. Safety of lasolacid in unapproved species has not been established.

Amount: 25 (0.0027 percent) to 30 (0.0033 percent) grams Lasalocid sodium per ton of feed.

Indications: For improved feed efficiency and increased rate of weight gain

Limitations: In Type C feeds. For cattle fed in confinement for slaughter only. Feed continuously in complete feed to provide not less than 250 milligrams nor more than 360 milligrams of lasalocid sodium activity per head per day. Feeding undiluted, mixing errors, or inadequate mixing may result in excess lasolacid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing

lasalocid as ingestion may be fatal. Safety of lasalocid in unapproved species has not been established.

Amount: 68 (0.0075 percent) to 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*

Limitations: Hand feed at a rate of 1 milligrams of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 milligrams of lasalocid per head per day. Feeding undiluted, mixing errors, or inadequate mixing may result in excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid in unapproved species has not been established.

Cattle (replacement calves not veal)

Amount: 68 (0.0075 percent) to 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For control of coccidiosis caused by *E. bovis* and *E. zuernii*

Limitations: In milk replacer powder. Hand feed at a rate of 1 milligram of lasalocid per 2.2 pounds body weight per day. Include on labeling warning : "A withdrawal period has not been established for lasalocid in preruminating calves. Do not use in calves to be processed for veal."

Amount: 20 (0.0022 percent) to 30 (0.0033 percent) grams lasalocid sodium per ton of feed.

Indications: For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg per head per day have not been shown to be more effective than 200 mg per head per day.

Limitations: Feed continuously at a rate of not less than 60 milligrams nor more than 300 milligrams of lasalocid per head per day when on pasture. The drug must be contained in at least 1 pound of feed. Feeding undiluted, mixing errors, or inadequate mixing may result in excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid in unapproved species has not been established.

Amount: 1,440 grams per ton (0.16 percent).

Indications: For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg per head per day have not been shown to be more effective than 200 mg per head per day.

Limitations: Feed continuously on a free-choice basis at a rate of 60 to 200

Dosage Amount,  
Indications  
& Limitations

milligrams lasalocid per head per day. Each use of this Type C free-choice feed must be the subject of an approved FD-1900 as provided in section 510.455.

Specifications: It is used as a free-choice mineral Type C feed as follows:

----- Ingredient Percent International  
feed number

Defluorinated Phosphate 35.9 6-01-080 (20.5% Ca 18.5% P) Sodium Chloride (Salt) 20.0 6-04-152 Calcium Carbonate 18.0 6-01-069 (38% Ca) Cottonseed Meal 10.0 5-01-621 Potassium Chloride 3.0 6-03-755 Selenium Premix 3.0 (0.02% Se) (see note\* below) Dried Cane Molass 2.5 4-04-695 Magnesium Sulfate 1.7 6-02-758 Vitamin Premix (see note\* below) 1.4 Magnesium Oxid 1.2 6-02-756 Potassium Sulfate 1.2 6-06-098 Trace Mineral Premix (see note\* below) 1.04 Bovatec Premix (68 g/lb) (see note\*\*) 1.06 -----

\* Note: Content of this vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with Sec. 573.920 of this chapter. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18). \*\*Note: To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses. -----

Cattle (pasture: slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)

Amount: 1,440 grams per ton (0.16 percent).

Indications: For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg per head per day have not been shown to be more effective than 200 mg per head per day.

Limitations: Feed continuously on a free-choice basis at a rate of 60 to 200 milligrams lasalocid per head per day. Each use of this Type C free-choice feed must be the subject of an approved FD-1900 as provided in section 510.455.

Specifications. It is used as a ruminant free-choice liquid Type C feed as follows:

----- Ingredient Percent International  
feed number -----  
Cane Molasses  
55.167 4-13-241 Condensed Molasses 24.0 . . . . Fermentation Solubles.  
50% Urea Solution (23% N) 12.0 . . . . Ammonium Polyphosphate Solution  
1.0 6-08-42 Phosphoric Acid (54%) 3.0 6-03-707 Xanthan Gum 0.05  
8-15-818 Water 4.0 . . . . Trace Mineral Mix (see note\* below) 0.5 . . . .  
Vitamin Premix (see note\* below) 0.2 . . . . Lasalocid Type A medicated  
article 0.083 . . . . (90.7 g/lb) (see note\*\* below)

----- Note\*: Content of vitamin and trace mineral premixes may be varied; however, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with Sec. 21CFR573.920. EDDI should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18). Note\*\*: To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)

Amount: 150 grams per ton (.017 percent).

Indications: For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

Limitations. For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day. Each use of this free-choice liquid Type C feed must be the subject of an approved FD-1900 as in Sec. 510.455 of this chapter.

Specifications. It is used as a free-choice, loose mineral Type C feed as follows:

----- Ingredient International Percent  
feed number -----  
Monocalcium Phosphate (21% P) 57.50 6-01-082 Salt 17.55 6-04-152 Distillers Dried Grains w/Solubles 5.40 5-28-236 Dried Cane Molasses (46% Sugars) 5.20 4-04-695 Potassium Chloride 4.90 6-03-755 Trace Mineral/Vitamin Premix 3.35 . . . . . (see note\* below) Calcium Carbonate (38% Ca) 2.95 6-01-069 Mineral Oil 1.05 8-03-123 Magnesium Oxide (58% Mg) 1.00 6-02-756 Iron Oxide (52% Fe) 0.10 6-02-431 Lasalocid Type A Medicated Article 0.80 . . . . . (68 g/lb) (see note\*\* below) -----

\*Note: Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21CFR573.920. EDDI should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18). \*\*Note: To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

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Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef

replacement heifers):

Amount. 1,088 grams per ton.

Indications for use.

For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

Limitations. Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

Sheep (confinement) Amount: 20 (0.0022 percent) to 30 (0.0033 percent) grams Lasalocid sodium per ton of feed.

Indications: For the prevention of coccidiosis caused by *Eimeria ovina*, *E. crandallis*, *E. ovinoidalis* (*E. ninakohlyakimovae*), *E. parva*, and *E. intricata*

Limitations: In Type C feeds. For sheep maintained in confinement. Feed continuously in complete feed to provide not less than 15 milligrams nor more than 70 milligrams of lasalocid sodium activity per head per day depending on body weight.

Rabbits

Amount: 68 (0.0075 percent) to 113 (0.0125 percent) grams Lasalocid sodium per ton of feed.

Indications: For prevention of coccidiosis caused by *Eimeria stiedae*.

Limitations: Feed continuously as sole ration up to 6 and 1/2 weeks of age.

Tolerances

Tolerances for lasalocid residues are established as follows:

1. Cattle: The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million  
2. Chickens: (I) Skin with adhering fat (the target tissue). The tolerance for parent lasalocid (the marker residue) is 1.2 parts per million. (ii) Liver. The tolerance for parent lasalocid (the marker residue) is 0.4 part per million.  
3. Turkeys: (I) Skin with adhering fat (the target tissue). The tolerance for parent lasalocid (the marker residue) is .4 part per million. (ii) Liver. The tolerance for parent lasalocid (the marker residue) is 0.4 part per million.  
4. Rabbits: The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million.  
5. Sheep: The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 1.0 part per million

