

VENTIPULMIN- clenbuterol syrup
Boehringer Ingelheim Animal Health USA Inc.

Ventipulmin® Syrup
(clenbuterol HCl)

Approved by FDA under NADA # 140-973

For oral use in horses only

Caution:

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

Caution:

Federal law prohibits the extralabel use of this drug in food animals.

Each mL contains:

Clenbuterol HCl 72.5 mcg

Description:

Clenbuterol (4-amino-alpha-[(tert-butylamino) methyl]-3, 5-dichlorobenzyl alcohol hydrochloride) is a beta-2-adrenergic agonist which provides bronchodilating properties as well as other effects, with minimum effect on the cardiovascular system. It is provided as a colorless, palatable syrup. VENTIPULMIN Syrup (clenbuterol hydrochloride) is antagonized by beta-adrenergic blocking agents.

Indications:

VENTIPULMIN Syrup (clenbuterol hydrochloride) is indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

Contraindications:

VENTIPULMIN Syrup antagonizes the effects of prostaglandin F₂ α and oxytocin. VENTIPULMIN Syrup should not be used in pregnant mares near term. Because tachycardia may occur, VENTIPULMIN Syrup should not be used in horses suspected of having cardiovascular impairment.

Warning:

The effect on reproduction in breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not

recommended.

Human Warnings:

Not for use in humans. Do not use in horses intended for human consumption. Keep out of reach of children. In case of accidental ingestion, contact a physician immediately. Ingestion of VENTIPULMIN Syrup may cause undesirable reactions. Clenbuterol, like other beta adrenergic agonists, can produce significant cardiovascular effects in some people as evidenced by elevated pulse rate, blood pressure changes and/or ECG changes.

Dosage and Administration:

Administer orally twice a day (b.i.d.). Initial dose is 0.5 mL/100 lbs body weight (0.8 mcg/kg) twice daily.

Dosage Schedule:

Initial dosage: administer 0.5 mL/100 lbs (0.8 mcg/kg) for 3 days (6 treatments); If no improvement, administer 1.0 mL/100 lbs (1.6 mcg/kg) for 3 days (6 treatments); If no improvement, administer 1.5 mL/100 lbs (2.4 mcg/kg) for 3 days (6 treatments); If no improvement, administer 2.0 mL/100 lbs (3.2 mcg/kg) for 3 days (6 treatments); If no improvement, horse is non-responsive to clenbuterol and treatment should be discontinued. Recommended duration of treatment at effective dose is 30 days. At the end of this 30-day treatment period, drug should be withdrawn to determine recurrence of signs. If signs return, the 30-day treatment regimen may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated.

Directions for Administration:

Remove safety cap and seal; replace with enclosed plastic dispensing cap. Remove cover from dispensing tip and connect syringe (without needle). Draw out appropriate volume of VENTIPULMIN Syrup. Administer orally to the horse. Replace cover on dispensing tip to prevent leakage.

Dosage Calculation Chart

Lbs. Body Weight	mL/treatment at 0.5 mL/100# (0.8 mcg/kg)	mL/treatment at 1.0 mL/100# (1.6 mcg/kg)	mL/treatment at 1.5 mL/100# (2.4 mcg/kg)	mL/treatment at 2.0 mL/100# (3.2 mcg/kg)
500	2.5	5.0	7.5	10.0
600	3.0	6.0	9.0	12.0
700	3.5	7.0	10.5	14.0
800	4.0	8.0	12.0	16.0
900	4.5	9.0	13.5	18.0
1000	5.0	10.0	15.0	20.0
1100	5.5	11.0	16.5	22.0

1200	6.0	12.0	18.0	24.0
1300	6.5	13.0	19.5	26.0
1400	7.0	14.0	21.0	28.0
1500	7.5	15.0	22.5	30.0
1600	8.0	16.0	24.0	32.0
1700	8.5	17.0	25.5	34.0
1800	9.0	18.0	27.0	36.0

Administer two treatments per day.

Precaution:

The safety cap should be placed on the bottle when not in use.

Adverse Reactions:

Mild sweating, muscle tremor, restlessness, urticaria and tachycardia may be observed in some horses during the first few days of treatment. May cause elevated creatine kinase (CK) serum levels. Ataxia was observed in 3 out of 239 horses (1.3%) in clinical studies. To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

How Supplied:

VENTIPULMIN Syrup is available in 100 mL and 330 mL plastic bottles containing 72.5 mcg clenbuterol HCl per mL.

NDC 0010-3017-02 – 100 mL, NDC 0010-3017-03 – 330 mL

Storage:

Store at or below 25°C (77°F). Avoid freezing.

VENTIPULMIN is a registered trademark of Boehringer Ingelheim Vetmedica GmbH.

Marketed by:

Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

Principal Display Panel - 330 mL Container Label

NDC 0010-3017-03

Ventipulmin® Syrup

Clenbuterol HCl 72.5 mcg/mL

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

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NDC 0010-3017-03
Ventipulmin[®] Syrup
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330 mL

Each mL contains; Clenbuterol HCl 72.5 mcg.

Indications; VENTIPULMIN Syrup (clenbuterol hydrochloride) is indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

Contraindications; VENTIPULMIN Syrup antagonizes the effects of prostaglandin F₂ α and oxytocin. VENTIPULMIN Syrup should not be used in pregnant mares near term. Because tachycardia may occur, VENTIPULMIN Syrup should not be used in horses suspected of having cardiovascular impairment.

Dosage and Administration: Refer to the package insert attached to this label for complete dosage and administration information.

Storage: Store at or below 25°C (77°F). Avoid freezing.

Warning: The effect on reproduction in breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended.

Human Warnings: Not for use in humans. Do not use in horses intended for human consumption. Keep out of reach of children. In case of accidental ingestion, contact a physician immediately. Ingestion of VENTIPULMIN Syrup may cause undesirable reactions. Clenbuterol, like other beta adrenergic agonists, can produce significant cardiovascular effects in some people as evidenced by elevated pulse rate, blood pressure changes and/or ECG changes.

Precaution: The safety cap should be placed on the bottle when not in use.

Marketed by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

 **Boehringer
Ingelheim**

Made in Mexico
301704-06

Principal Display Panel - 330 mL Display Carton - Front and Side Panel

NDC 0010-3017-03

Ventipulmin[®] Syrup

Clenbuterol HCl 72.5 mcg/mL

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For oral use in horses only

Approved by FDA under NADA # 140-973

158657-002

Lot No. Exp. Date

Ventipulmin® Syrup
Clenbuterol HCl 72.5 mcg/mL
For oral use in horses only
Net Contents: 330 mL
Approved by FDA under NADA # 140-973

NDC 0010-3017-03

Ventipulmin® Syrup

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330 mL

 **Boehringer
Ingelheim**

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Dosage and Administration: Refer to the package insert attached to label for complete dosage and administration information.

Contains Dispensing Cap.

VENTIPULMIN is a registered trademark of Boehringer Ingelheim Vetmedica GmbH.

Made in Mexico
301705-05

Principal Display Panel - 330 mL Display Carton - Back and Side Panel

NDC 0010-3017-03

Ventipulmin[®] Syrup
Clenbuterol HCl 72.5 mcg/mL

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Boehringer
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See package insert attached to label for complete details.

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Boehringer Ingelheim
Animal Health USA Inc.
Duluth, GA 30096

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VENTIPULMIN
clenbuterol syrup

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-3017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLENBUTEROL HYDROCHLORIDE (UNII: GOR5747GWJ) (CLENBUTEROL - UNII:XTZ6AXU7KN)	CLENBUTEROL HYDROCHLORIDE	0.0725 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-3017-02	1 in 1 CARTON		
1		100 mL in 1 BOTTLE, PLASTIC		
2	NDC:0010-3017-03	1 in 1 CARTON		
2		330 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140973	01/12/2011	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 6/2022

Boehringer Ingelheim Animal Health USA Inc.