Pr

RESPIPULMIN™

(Clenbuterol hydrochloride syrup)

For Veterinary Use Only
DIN 02380803
Bronchodilator syrup for oral use in horses only

Description: A colourless, slightly opalescent, viscous syrup with a hardly perceptible odour. Each mL of syrup contains 0.025 mg (25 µg) of 4-amino-α-[(ter.-butyl-amino) methyl]-3,5,dichlorobenzylalcohol hydrochloride (clenbuterol hydrochloride), and 2.02 mg of methylparahydroxybenzoate and 0.26 mg of propylparahydroxybenzoate as preservatives.
Indications: RESPIPULMIN™ is recommended as an aid for the treatment of respiratory disease in horses where it is considered that airway obstruction is due to bronchospasms.
Dosage and Administration: Twice daily oral administration of 0.8 µg of clenbuterol per kg body weight. This is equivalent to one stroke (4 mL) of the metered dosing pump (provided with each package) for each 125 kg (275 lbs.) b.w. twice daily on the grain portion of the feed.
Contra-indications: Do not use with β-adrenergic agents. Due to a potential risk of increasing the peripheral vasodilating effect of clenbuterol, it is not recommended that corticosteroids be used in conjunction with RESPIPULMIN™. Clenbuterol antagonizes the effects of prostaglandins $F_2\alpha$ and oxytocin. The action of clenbuterol is antagonized by β-adrenergic blocking agents.
Cautions: If used during pregnancy, RESPIPULMIN™ must be discontinued at the expected time of delivery, since uterine contractions may be abolished under its influence. The effect on fertility of breeding stallions has not been determined.
WARNINGS: FEDERAL LAW PROHIBITS THE ADMINISTRATION OF THIS PREPARATION TO ANIMALS THAT PRODUCE FOOD OR THAT ARE INTENDED FOR CONSUMPTION AS FOOD. KEEP OUT OF REACH OF CHILDREN. TAKE CARE TO AVOID SKIN AND EYE CONTACT. IN CASE OF SKIN CONTACT, WASH AFFECTED AREA THOROUGHLY. IF IRRITATION OCCURS/PERSISTS SEEK MEDICAL ADVICE. IN THE CASE OF ACCIDENTAL EYE CONTACT, FLUSH THOROUGHLY WITH CLEAN WATER AND SEEK MEDICAL ADVICE. DO NOT EAT OR DRINK, WHILE HANDLING THIS PRODUCT. WASH HANDS THOROUGHLY AFTER USING THE PRODUCT.
Clinical pharmacology: The treatment of respiratory disease in horses constitutes a problem that has not been satisfactorily solved, even though many efficient therapeutic measures are available today. Pharmacological treatment finds its particular application at the level of either some exogenous stimulus, e.g., infection or some mechanism of bronchial obstruction, e.g., bronchospasm and/or accumulation of mucus. Bronchial obstruction, due to the accumulation of secretions, has been acted upon by mucolytic and expectorant drugs while bronchial obstruction caused by bronchospasm is relieved by sympathomimetic amines, anticholinergics, corticosteroids and xanthine derivatives.
The sympathomimetic amines have attracted special interest, their clinical application having originated in the demonstrated existence of cellular adrenergic receptors, which are called alpha, beta and gamma according to their response to stimuli. The beta-receptors were further subdivided into beta-1 and beta-2. Stimulation of beta-2 receptors causes a relaxation of the smooth musculature of the bronchi and uterus, and of the beta-1 receptors of the intestinal tract and an increase in cardiac frequency.
Especially interesting for the treatment of the respiratory diseases are the beta-mimetic drugs used as bronchodilators. The phenomenon of bronchial spasm is determined by a defect in metabolism at the cellular level and is seen as an increased sensitivity in the bronchial musculature to some chemical mediators such as histamine, acetylcholine, etc., with the consequent phenomenon of bronchospasm.
Beta-2 stimulant sympathomimetics, resolve bronchial spasm and consequently improve pulmonary ventilation. In many disease states, both subacute and chronic, the pathological state and the physical phenomena can persist even when the aetiological agent has ceased in its action. The disease still exists due to the continued disturbances of the physiological processes.
Clenbuterol, the active ingredient in RESPIPULMIN™, is a sympathomimetic amine and has been the subject of intensive research in both man and domestic animals. Due to its chemical structure, a high degree of selectivity for the beta-2 receptor sites in the body has been achieved providing intense bronchodilating properties with minimum effect on the cardiovascular system.
Other properties attributed to clenbuterol include excellent absorption from the gastrointestinal tract following oral administration so that the oral and parenteral dose rates are identical as 0.8 µg per kg body weight.
The duration of effect is long-lasting and in the range of 6-8 hours after a single application and 12 hours on repeated twice daily dosing. Hence, once a plateau has been reached after 3-5 days, twice daily administration by the oral route has been found to give satisfactory level of medication.
Safety and Efficacy: In clinical trials, the effects of clenbuterol on pulmonary function and clinical response were assessed in horses suffering from a variety of respiratory conditions including chronic obstructive pulmonary disease (COPD).
The horses responded by a marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvement.
Other results showed a significant reduction in resistance to airflow and clinical improvement of the animal's respiratory pattern
There were no significant side effects due to the treatment with clenbuterol in any of the clinical trials. In those conditions, where concurrent infection existed supplementary treatment with chemotherapeutic agents was instituted.
Storage: 15-30 ºC (59-86 ºF) - Protect from light.
Presentation: RESPIPULMIN™ is presented in bottles of 355 mL of syrup containing 0.025 mg of clenbuterol hydrochloride per mL.

Manufactured for:
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