

WARNINGS: animals treated with ARTEROL® should not be intended for human consumption. Containers must be disposed of in accordance with local regulations. Keep out of reach of children and domestic animals.

PRESENTATION: Vial (x 2) with powder for reconstitution. Vial (x 2) with diluent solution. Syringe and needle (x 2).

For Mexico: Sale requires a quantified medical prescription. For exclusive use by veterinarians.

Detailed technical information is available to the veterinary body.

This medication is an original research product
by Laboratorio Fundacion. It is the first
development of the active ingredient in
Veterinary Medicine.

USE IN VETERINARY MEDICINE
SELL UNDER PRESCRIPTION
DO NOT SOTRE / KEEP
DO NOT KEEP/DO NOT STORE BY
ABOVE 25 °C. DO NOT FREEZE.

SENASA
Cert. N° 01-258
Est. Elab. N° 7112
D.T.: M.V. LADAGA, G.



LR 07-2024

ARTEROL®
EFORMOTEROL FUMARATE DIHYDRATE

Laboratorio
FUNDACION

MADE IN ARGENTINA

INJECTABLE

COMPOSITION: Sterile powder vial. Contains Eformoterol Fumarate Dihydrate 0.04 mg. Excipient q.s. 100 mg. Diluent solution vial.

THERAPEUTIC ACTION: ARTEROL® is characterized by being a potent bronchodilator with vasoactive effects on the small circuit (pulmonary area) with a prolonged action.

INDICATIONS: It is indicated in:

A) Bronchial conditions that involve a reversible obstructive process. This includes, for example, chronic bronchitis, bronchiolitis, chronic obstructive pulmonary disease (COPD), with or without pulmonary emphysema. Additionally, its effect implies an increase in bronchial clearance (mucociliary clearance) and strong inhibition of the release of inflammatory products (histamine). This last factor is of great importance in stabled horses exposed to various allergens.

B) It is optimal in pre-exercise therapy, improving performance through adequate oxygenation. There is a prompt restoration of physiological parameters (heart rate, respiratory rate, and blood pressure) 40 minutes post-exercise. The effect of decreased frequency and increased respiratory depth, resulting from improved oxygenation, is noticeable.

C) In exercise-induced pulmonary hemorrhage (EIPH), it causes an increase in hematosi (O2 exchange) through bronchodilation and increased perfusion through vasodilation. This vasoactive action, along with the restoration of damaged endothelium and the unique decrease in microvascular permeability of ARTEROL®, clinically results in a significant reduction in bleeding, whether endoscopic or manifest (epistaxis).

ADMINISTRATION ROUTE: Intramuscular in a single injection site. It should not be administered intravenously, by inhalation, or intratracheally.

DOSAGE: ARTEROL® is prepared using the entire diluent solution, injecting it into the vial containing the powder. Shake to form the solution.

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Este es un medicamento con investigación
original de Laboratorio Fundacion. Es el primer
desarrollo del principio activo en Medicina
Veterinaria.

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	<p>Once reconstituted, the solution cannot be stored.</p> <p>The dosage depends on the type and severity of the condition. The following dosages can be considered as guidelines:</p> <p>1) 1 to 2 vials (0.040 to 0.080 mg total) in animals weighing 300 to 600 kg (if using two vials, it is recommended to load them into the same syringe for a single application).</p> <p>2) ½ to 1 vial (0.020 to 0.040 mg total) in animals weighing less than 300 kg and in foals.</p> <p>The clinical action duration of ARTEROL® in horses is over 10 hours, allowing for dose repetition or sustained treatment every 12 hours. The duration of the treatments is at the discretion of the attending professional, but the following can be considered:</p> <p>A) In obstructive bronchopulmonary conditions (e.g., bronchitis or bronchiolitis) to facilitate ventilation and improve hematosis, maintain a dose every 12 hours (½ to 1 vial according to weight) until signs recover. If bacterial infection is suspected, it is advisable to incorporate an antibiotic into the therapy.</p> <p>B) In chronic pathologies (e.g., chronic bronchitis, COPD) and mild to moderate cases of EIPH (endoscopic view up to two crosses), treatment can be administered prior to physical activity (1 vial for generally adult animals over 300 kg) to enhance pulmonary function and reduce bleeding. Extensive studies conducted by Laboratorio FUNDACION on PSC in training have determined that the optimal administration time is two hours prior to exercise.</p> <p>C) If the hemorrhagic pathology is severe (three crosses or manifest external bleeding), it is advisable to maintain a sustained treatment (2 vials) every 12 hours for at least 5 days, with the animal at rest. Subsequently, activity is resumed progressively, maintaining the treatment with one application 2 hours before exercise, as mentioned in point B.</p> <p>It was determined in trials that there was clinical significance in the occurrence of localized sweating at the injection site. This could be evaluated as an intensity of clinical response and dose adjustment, as</p>		<p>a possible relationship was observed between the absence of sweating and reduced efficacy.</p> <p>SIDE EFFECTS: ARTEROL® has an adequate therapeutic margin; clinical trials showed, in order of frequency: localized sweating at the injection site, which can extend to the neck and inguinal area and, less frequently, to the rest of the trunk; muscle tremor (infrequent), rash (infrequent), yawning, nervousness, penile relaxation (very infrequent). In toxicity studies at maximum dose and overdose, conducted by Laboratorio FUNDACION on mixed breed and PSC horses, no severe signs were observed. There were no changes in potassium, liver function tests, muscle enzymes, urea, creatinine, or blood values. A notable hyperglycemia was observed between the first and eighth hours post-inoculation, exceeding the maximum values of 110 mg%.</p> <p>The following signs, detected in experimental animals, were not observed: paradoxical bronchospasm (since its occurrence is by inhalation or oral route), conjunctival and/or palpebral irritation, hypokalemia.</p> <p>CONTRAINDICATIONS: Despite not showing changes in cardiovascular parameters and not causing drops in blood potassium, special care should be taken if animals are suspected to have cardiac compromise (arrhythmia, third-degree block). In parturient animals, it may inhibit labor.</p> <p>DRUG INTERACTIONS: Although a hypokalemic effect is not observed, the concomitant use of diuretics, glucocorticoids, and xanthines may accelerate its onset. The simultaneous use of phenothiazines, antihistamines, and quinidine may accelerate the occurrence of ventricular arrhythmias. Sympathomimetic drugs may enhance the side effects of ARTEROL®, and beta-blockers may inhibit its therapeutic action.</p> <p>PRECAUTIONS: For Argentina, in case of accidental ingestion, call the National Poison Control Center: 0800-333-0160; Posadas Hospital 4658-7777; Children's Hospital 4962-6666/2247.</p>	
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