

ARTEROL[®]

(Eformoterol Fumarate Dihydrate)



INJECTABLE

Made in Argentina

Composition: Vial with sterile powder. Contains Eformoterol (as fumarate dihydrate) 0.04 mg. Excipient q.s 100 mg.
Vial with diluting solution.

Therapeutic action: ARTEROL[®] is characterized to be a potent bronchodilator with a vasoactive effect in the small circuit (pulmonary area) with prolonged action.

Indications: It is indicated in:

- A) Bronchial diseases that have a reversible obstructive process. This implicates i.e. chronic bronchitis, bronchiolitis, chronic obstructive pulmonary disease (COPD) with or without pulmonary emphysema. Another effect implies an increase in bronchial sweep ness (mucociliary clearance) and strong inhibition of the liberation of inflammatory products (histamine). This last factor is of paramount importance in stalled horses submitted to different allergens.
- B) It is optimal for pre-exercise therapy, improving performance due to an adequate oxygenation. A swift return to physiological parameters can be observed 40 minutes after exercise. Also a notorious effect on respiratory rate reduction and an increase in ventilatory depth can be observed due to an oxygenation improvement.
- C) In exercise induced pulmonary hemorrhage (EIPH) increases hemato-sis (O₂ exchange) due to bronchodilatation and increase in perfusion due to vasodilatation. This vasculoactive action joined to the restitution of the damaged endothelium and the reduction of the microvascular permeability unique to ARTEROL[®] is manifested clinically by a notorious reduction in bleeding seen by endoscopy or shown as epistaxis.

Administration: Intramuscularly, in a single injection. *Must not administered intravenously.*

Dosage: ARTEROL is prepared injecting all the diluent's vial content into the vial containing the powder. Shake till final solution is made. Once reconstituted can not be preserved.

Dose depends on the type of problem and the graveness of the situation. As an orientation the following doses can be considered:

- 1) 1 to 2 vials (0.040 to 0.080 mg total dose) in animals weighing 300 to 600 kg (in cases where two vials are going to be used it is recommended to load the whole content into a single syringe in order to make a single injection.)
- 2) ½ to 1 vial (0.020 a 0.040 mg total dose) in animals weighing less than 300 kg and colts.

It has been determined a duration of the clinical action of ARTEROL in horses of more than 10 hours which enables in case of dose repetition or prolonged treatment an injection every 12 hours.

Treatment duration is under the professional in charge consideration, but it can be considered:

A) In an obstructive bronchopulmonary situation (i.e. bronchitis or bronchiolitis) to enhance ventilation and improve hematosi, a dose every 12 hours can be used (½ to 1 vial according to body weight) until recovery. It is advisable to incorporate the appropriate antibiotic therapy if there is a suspicion of an associated bacterial infection.

B) In chronic disease (i.e.chronic bronchitis, COPD), and in mild to medium EIPH (endoscopic diagnosis up to 2 +) a pre exercise treatment can be done (1 vial because the animals usually involved are adults weighing more than 300 kg) to increase pulmonary function and to reduce bleeding.

Over extensive studies made by Laboratorio FUNDACION on thoroughbred in training, it could be determined that the optimum time for supplying the dose is 2 hours pre-exercise.

C) If the hemorrhagic disease is severe (3 + or external bleeding) it is advisable to maintain a sustained treatment (2 vials) every 12 hours, for 5 days minimum leaving the horse to rest.

Activity will be resumed later in a progressive manner treating the patient 2 hours before exercise as was advised on item B.

During research and trial the appearance of sweatiness at the injection site with a clinical significance was determined. This can be used to determine the intensity of the clinical response and dose adjustment because a possible relationship between its absence and the reduction in efficacy was observed.

Side effects: ARTEROL[®] has an adequate therapeutic margin; during clinical trials the following was observed: appearance of sweatiness at the injection site which can be extended up to the neck and inguinal fossa, and less frequently to the rest of the trunk; muscular tremor (very infrequent); rash (very infrequent); defecation; nervousness and penile relaxation. During research related to toxicity at maximum dose and overdose carried on by Laboratorio FUNDACION in mongrel and thoroughbred horses no severe adverse signs were appreciated. There were no changes neither in K, hepatogram, muscular enzymes, BUN, creatinine nor blood values, and only a notorious hyperglycemia was evidenced between 1 hour up to 8 hours post injection overriding the maximum value of 110 mg %.

No evidence of the following signs appeared in lab animals were determined: paradoxical bronchospasm (its appearance is via inhalation), conjunctival and/or palpebral irritation, hypokalemia.

Contraindications: Even though not showing changes in cardiovascular parameters and not decreasing blood K, special care must be taken with animals suspected to have a cardiac disease (arrhythmia, third degree block). Animals in labor can have inhibition of parturition.

Usage restrictions: *Animals treated with ARTEROL[®] must not be used for human consumption.*

Drug interaction: No observation of the hypokalemic effect being observed, the associated use of diuretics, glucocorticoids and xanthines may speed up its appearance. Use of phenothiazines, antihistamines and quinidine may accelerate the manifestation of ventricular arrhythmia. Sympathomimetic drugs may enhance collateral effects of **ARTEROL**® and beta blockers may inhibit its therapeutic action.

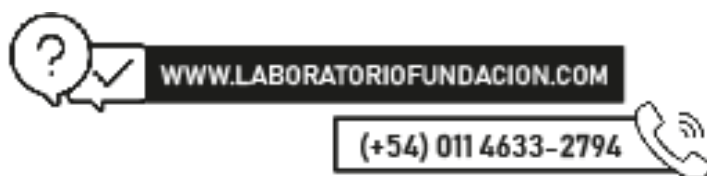
Presentation: Vial (x 2) with powder. Vial (x 2) with diluent solution. Syringe and needle (x 2).

Sold under archived prescription.

Detailed technical data may be requested by Veterinarians.

THIS IS AN ORIGINAL RESEARCH MEDICAMENT MADE BY
LABORATORIO FUNDACION

This is the first development of this principle in veterinary medicine.



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