



# Aservo® EquiHaler®

(ciclesonide inhalation spray)

For intranasal inhalation in horses only

## HIGHLIGHTS

- No statistically significant decrease in serum cortisol level<sup>1</sup>
- Accepted by >93% of horses<sup>1</sup>
- Proven safety and efficacy under controlled and field conditions<sup>1,2,3</sup>
- Prodrug ciclesonide converted in the airway epithelium to pharmacologically active des-ciclesonide<sup>3</sup>
- Designed to consistently deliver a predetermined dose of ciclesonide in a slow-moving mist (Soft Mist™)

## DESCRIPTION

ASERVO EQUIHALER is a nonpressurized metered dose inhaler and drug cartridge combination containing a solution of 30 mg/mL of the prodrug ciclesonide, which is enzymatically converted to the pharmacologically active metabolite desisobutrylciclesonide (des-ciclesonide) following inhalation. Des-ciclesonide is a glucocorticoid class of corticosteroid. Each actuation releases 343 mcg of ciclesonide.

## FEATURES

- ASERVO EQUIHALER is supplied as one inhaler with a pre-inserted cartridge, which contains inhalation solution for 140 treatment actuations (puffs), enough for a 10-day treatment course.
- Designed specifically for horses.
- Soft Mist™ Technology delivers medication in a slow-moving mist that is easily inhaled into the lower airway.<sup>2</sup>
- The prodrug ciclesonide is activated in the airway epithelium to pharmacologically active des-ciclesonide.<sup>3</sup>

## BENEFITS

- ASERVO EQUIHALER is designed to consistently deliver a predetermined dose of ciclesonide with each actuation.
- Soft Mist™ Technology delivers medication in a slow-moving mist that is easily inhaled into the lower airway.<sup>2</sup>
- No statistically significant decrease in serum cortisol level.<sup>1</sup>
- Prodrug reduces inflammation to decrease airway obstruction.<sup>3</sup>
- Accepted by >93% of horses.<sup>1</sup>
- Proven safety and efficacy under controlled and field conditions in over 600 horses – includes placebo and equihaler treated horses.<sup>1</sup>

## ADVANTAGES

A combination of a novel glucocorticoid (ciclesonide) and advanced inhalation technology (Soft Mist™ Inhaler) designed specifically for horses.

## INDICATION

ASERVO EQUIHALER is indicated for the management of clinical signs associated with severe equine asthma in horses.

## DOSAGE & ADMINISTRATION

For intranasal inhalation use only. ASERVO EQUIHALER may be used as part of the overall management of severe equine asthma in addition to other appropriate strategies to control clinical signs, such as environmental changes and bronchodilator therapy, as needed. The initial dose is 8 actuations (2,744 mcg ciclesonide) twice daily for 5 days, followed by 12 actuations (4,116 mcg ciclesonide) once daily for 5 days. Prior to use, please refer to the detailed instruction manual for the handling and use of ASERVO EQUIHALER.

## PRECAUTIONS/WARNINGS

ASERVO EQUIHALER has not been evaluated in pregnant or lactating mares. In a large clinical field study, the most common adverse reactions reported were coughing, nasal discharge, sneezing and nasal irritation/bleeding. Administration of corticosteroids may worsen existing bacterial, fungal or viral infection and may induce the first stage of parturition. Glucocorticoids should be used with caution in horses at a higher risk for laminitis. Secondary infections should be ruled out before prescribing ASERVO EQUIHALER. Inhaled corticosteroids should be used with caution, if at all, in horses with an active infection of the respiratory tract. Concurrent use of other anti-inflammatory drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs) or other corticosteroids, should be approached with caution. Due to the potential for systemic exposure, concomitant use of NSAIDs and corticosteroids may increase the risk of gastrointestinal, renal, and other toxicity. Consider appropriate wash-out times prior to administering NSAIDs or additional corticosteroids. Not for use in humans. Keep this and all medications out of the reach of children. In case of accidental inhalation, seek medical advice immediately and show the package insert or the product label to the physician. People with known hypersensitivity to ciclesonide or any of the excipients should avoid contact with ASERVO EQUIHALER.

Do not use in horses intended for human consumption.

## CONTRAINDICATIONS

Do not use in horses with known hypersensitivity to ciclesonide or corticosteroids.

## STORAGE

Store at 15-30°C (59-86°F), with excursions permitted up to 40°C (104°F). Protect from freezing.

Use within 12 days of activation.

## PRODUCT INFORMATION

Name	Code	Size
ASERVO EQUIHALER		



1. Freedom of Information Summary. 2020. Original New Animal Drug Application. Aservo® EquiHaler® (ciclesonide inhalation spray).

2. Dalby, R., Spallek, M. and Voshaar, T., 2004. A review of the development of Respimat® Soft Mist™ Inhaler. International Journal of Pharmaceutics, 283(1-2), pp.1-9.

3. Mukker, J.K., Singh, R.S.P. and Derendorf, H., 2016. Ciclesonide: a pro-soft drug approach for mitigation of side effects of inhaled corticosteroids. Journal of Pharmaceutical Sciences, 105(9), pp.2509-2514.

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