

# Important Safety Information



## **Aservo® EquiHaler® (ciclesonide inhalation spray)**

**Indication:** ASERVO EQUIHALER is indicated for the management of the clinical signs associated with severe equine asthma

### **IMPORTANT SAFETY INFORMATION:**

- Safe use of 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.
- Do not use in horses with known hypersensitivity to ciclesonide or corticosteroids.
- Clinical and experimental data have demonstrated that glucocorticoids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.
- Additionally, glucocorticoids administered during pregnancy can be teratogenic. Therefore, ASERVO EQUIHALER should only be used in pregnant mares if the potential benefit justifies the potential risk to the fetus.
- Administration of glucocorticoids may worsen existing bacterial, fungal, or viral infection.
- Secondary infections should be ruled out before prescribing ASERVO EQUIHALER.
- Inhaled glucocorticoids should be used with caution, if at all, in horses with active infection of the respiratory tract.
- If clinical signs do not improve or worsen despite administration of ASERVO EQUIHALER, the prescriber should consider additional diagnostic evaluation.
- Due to the potential for exacerbation of clinical signs of laminitis, glucocorticoids should be used with caution in horses with a history of laminitis, or horses otherwise at a higher risk for laminitis.
- Use with caution in horses with chronic nephritis, equine pituitary pars intermedia dysfunction (PPID), and congestive heart failure.
- Concurrent use of other anti-inflammatory drugs, such as non-steroidal 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.
- Do not use in horses intended for human consumption.

### **Storage Information:**

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.