

Aservo® EquiHaler® has been extensively studied for both safety and efficacy in clinical trials with more than 600 horses.

Pulmonary function in a mouldy hay challenge model²³

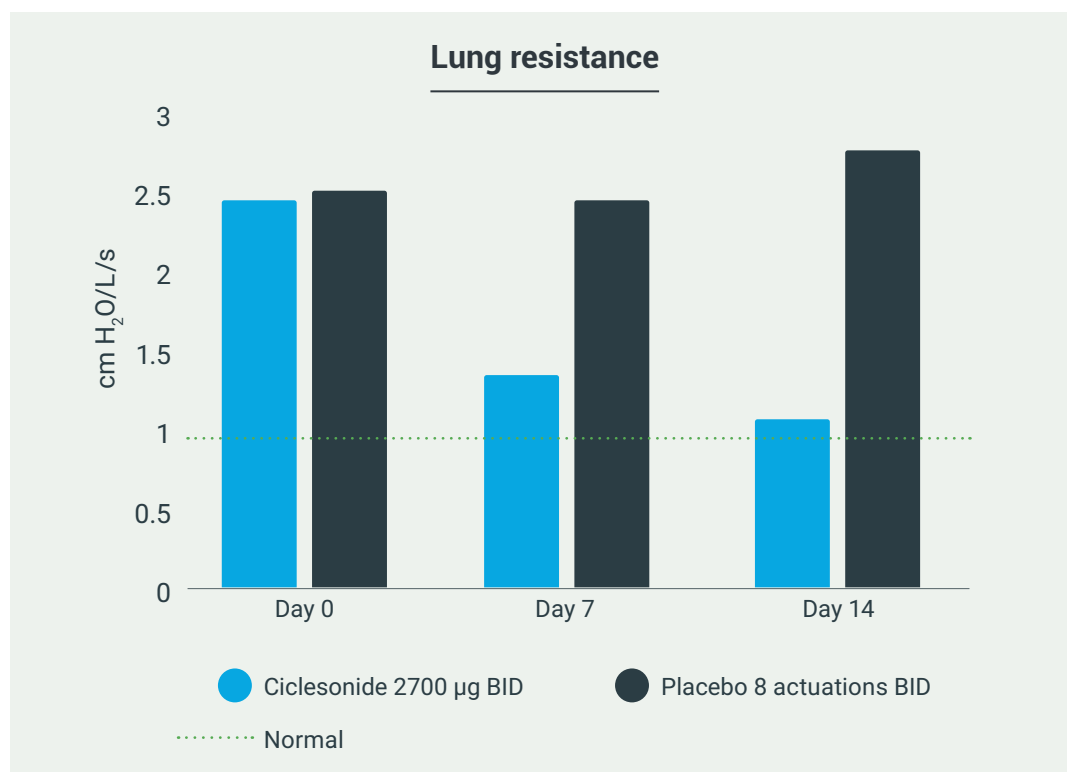
A cross-over placebo controlled, blinded, randomised study was performed in 8 horses to investigate the effects of different doses of inhaled ciclesonide on the pulmonary function of asthmatic horses undergoing experimentally induced airway obstruction in a mouldy hay challenge model.

Mouldy hay challenge model

- Proven experimental model to induce airway obstruction and clinical exacerbations in asthmatic horses²⁷.
- Each horse included in this study underwent a personalised mouldy hay challenge in order to induce a steady degree of airflow obstruction during a 2 week conditioning phase before treatment, and throughout the duration of the study.

Inhaled ciclesonide at 2,700µg twice daily significantly improved both pulmonary function and weighted clinical score on day 7, with a further improvement observed on day 14, when compared to placebo.

Pulmonary function is considered the gold standard for measuring response to treatment of severe equine asthma. The average lung resistance on day 0 was 2.5 cm H₂O/L/s, consistent with a diagnosis of severe equine asthma. A lung resistance of up to 1 cm H₂O/L/s is considered normal.



European clinical efficacy study²²

A prospective, multicentre, double blind, randomised, placebo-controlled clinical trial was conducted with 224 client owned horses by 24 vet clinics in 3 countries under field conditions.

To be included in the study horses had to have a diagnosis of severe equine asthma based on:

- History of chronicity of equine asthma previously responsive to administration of a bronchodilator, and/or glucocorticoid and/or change in environment
- Laboured breathing observed at rest and an abdominal lift score ≥ 1
- Weighted clinical score ≥ 11
- Duration of current episode over 14 days with observation of at least one clinical sign of moderate to severe equine asthma
- No environmental changes were allowed 2 weeks prior and throughout the study

A Weighted Clinical Score (WCS) was used by vets to monitor response to treatment with Aservo® EquiHaler® (at the licensed dose and duration) or placebo. This clinical score has been validated by pulmonary function testing and the average WCS of a horse on day 0 of the study was 15: which equates to a lung resistance of 2.5 cm H₂O/L/s, as per the previous study.

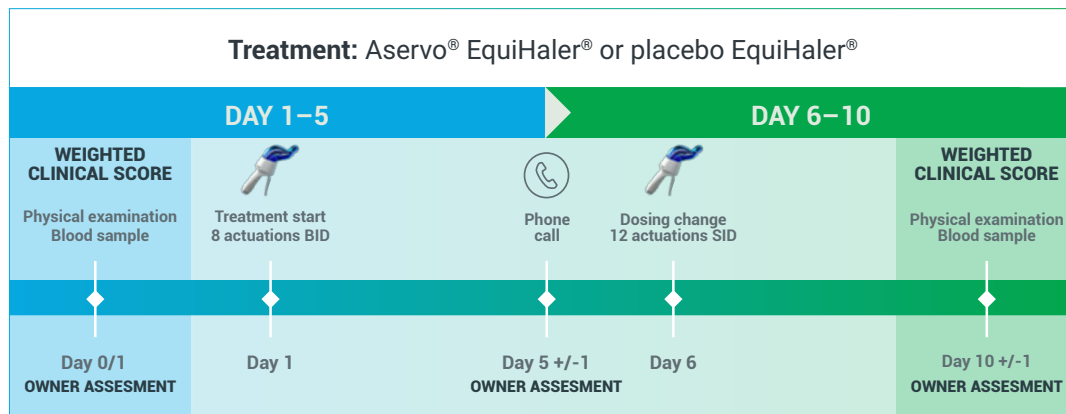
Weighted Clinical Score (WCS)

WCS is a total score (out of 23) assigned to an individual horse based on 9 clinical parameters. WCS has been positively correlated with severity of pulmonary obstruction as defined by pulmonary resistance in horses with severe equine asthma²³.

Pulmonary obstruction	R _L (cm H ₂ O/L/s)	Weighted Clinical Score
Mild	1.0–1.8	≤ 10
Moderate	1.8–2.5	11–14
Severe	>2.5	≥ 15

R_L, pulmonary resistance

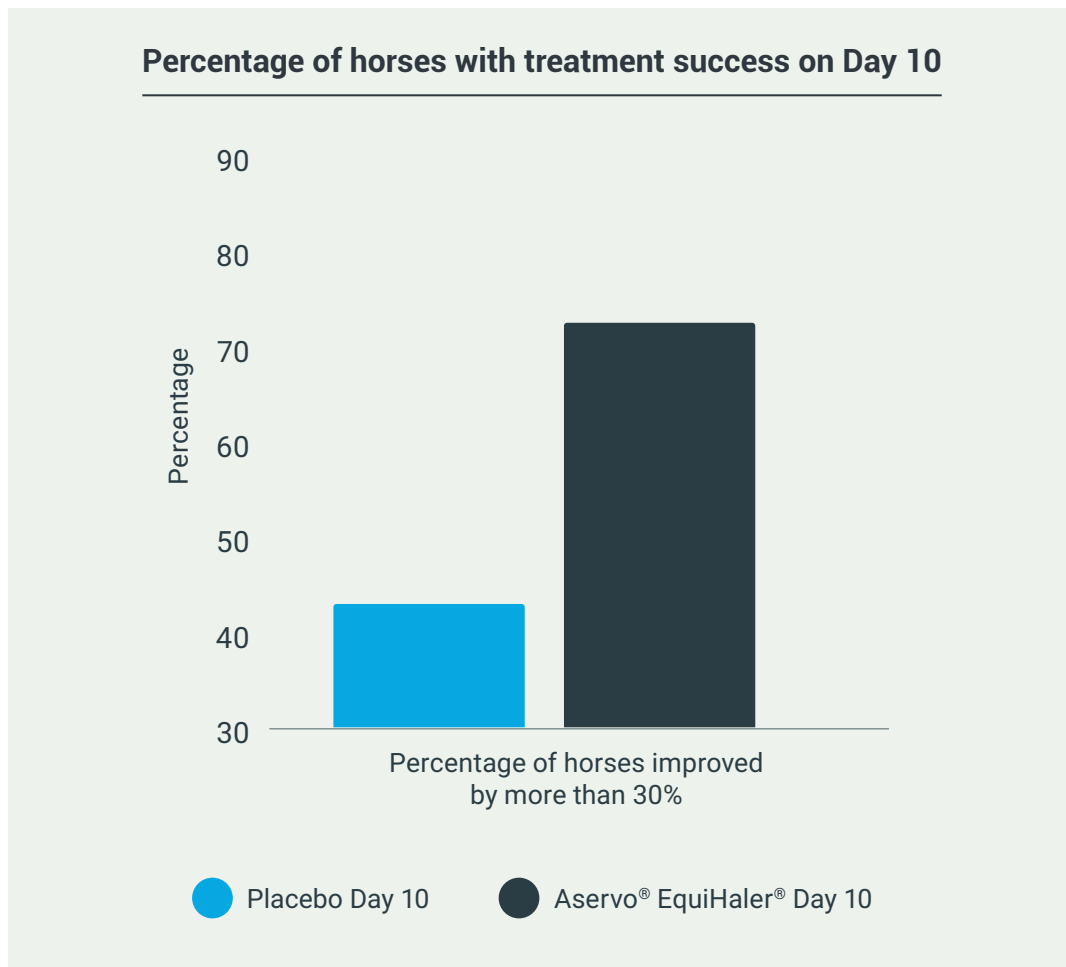
The study started on day 0 and continued to day 10 +/-1. All treatments were administered by the horse owners. The horses were randomly assigned to either treatment with Aservo® EquiHaler® or placebo and both the owners and investigators were blinded to which was administered. The owners were instructed not to change the horses' environment in any way during the trial.



Results

The mean WCS of Aservo® EquiHaler® treated patients on day 10 was 7.8, compared to a starting WCS of 15. This corresponds to a patient with severe pulmonary obstruction becoming mild, as per the definitions in the Weighted Clinical Score table.

Treatment with the Aservo® EquiHaler® was considered successful in 73.4% of horses receiving the treatment between day 0 and day 10 +/-1, as compared to placebo.



The results of this study demonstrate that:

- Aservo® EquiHaler® is effective in improving clinical signs related to severe equine asthma (including summer pasture-associated equine asthma)
- Horse acceptance of the Aservo® EquiHaler® is >95%³⁹

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