



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Aservo Equihaler (*ciclesonide*)

An overview of Aservo Equihaler and why it is authorised in the EU

What is Aservo Equihaler and what is it used for?

Aservo Equihaler is an anti-inflammatory medicine used to treat severe asthma in horses. Aservo Equihaler contains the active substance ciclesonide.

How is Aservo Equihaler used?

The medicine is available as a solution for inhalation and is given to horses through the left nostril using an inhaler. Aservo Equihaler can only be obtained with a prescription and should only be given if the veterinarian considers that the horse's temperament is suitable for safe and effective use of Aservo Equihaler.

All horses receive the same dose over 10 days. There is an initial dose of 8 actuations (releases) twice a day for the first five days followed by 12 actuations once a day from day 6 to 10.

For more information about using Aservo Equihaler, see the package leaflet or contact your veterinarian or pharmacist.

How does Aservo Equihaler work?

Ciclesonide is a prodrug, a substance that is converted to des-ciclesonide mainly in the horse's lung following inhalation. Des-ciclesonide belongs to a group of anti-inflammatory medicines known as corticosteroids. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors in various types of immune cells. This leads to a reduction in the release of substances that are involved in the inflammation process, thereby helping to keep the airways clear and open to allow the horse to breathe more easily.

What benefits of Aservo Equihaler have been shown in studies?

In a field study involving 220 horses with moderate to severe asthma lasting more than 2 weeks treatment with Aservo Equihaler was effective in 73% horses compared to 43% of horses receiving a dummy treatment. Treatment success was defined as an improvement by 30% or more in asthma signs consisting of cough, runny nose, flared nostrils, difficulty in breathing at rest, abnormal rate of breathing, windpipe sounds and abnormal chest sounds.

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What are the risks associated with Aservo Equihaler?

The most common side effect with Aservo Equihaler (which may affect up to 1 in 10 horses) is a slightly runny nose.

Aservo Equihaler must not be used in known cases of hypersensitivity to ciclesonide, to corticosteroids or to any of the other ingredients in Aservo Equihaler.

For the full list of restrictions, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The instructions for handling and use of the Aservo Equihaler are provided in the package leaflet.

Treatment with Aservo Equihaler should take place in well ventilated surroundings.

People who are hypersensitive (allergic) to ciclesonide or any of the other ingredients in the medicine should avoid contact with Aservo Equihaler.

Contact into the nose or inhalation of corticosteroids may cause inflammation of the nose, nasal discomfort, nosebleed, upper airway infection and headache. An aerosol filtering mask must be worn during handling and when giving the medicine. This prevents accidental inhalation in case of unintended release of actuations outside the nostril or without the nostril adapter.

The medicine can cause irritation to the eyes due to its ethanol content. Avoid contact with eyes. In case of accidental eye contact, rinse with large quantities of water.

In case of eye irritation or an adverse reaction due to accidental inhalation, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

The precautions above should be followed by the person giving the medicine and people in close proximity to the horse's head during treatment.

Pregnant women should not give the medicine.

If Aservo Equihaler is visually damaged, it should no longer be used.

It is essential to keep the medicine out of reach for children.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from horses treated with Aservo Equihaler is 18 days.

The medicine is not authorised for use in horses producing milk for human consumption.

Why is Aservo Equihaler authorised in the EU?

The European Medicines Agency decided that Aservo Equihaler's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Aservo Equihaler

Aservo Equihaler received a marketing authorisation valid throughout the EU on 28 January 2020.

Further information on Aservo Equihaler can be found on the Agency's website:
ema.europa.eu/medicines/veterinary/EPAR/aservo-equihaler.

This overview was last updated in November 2019.