

Aservo[®] Equihaler[®]

30 mg/ml

inhalation solution for horses

ciclesonide

140 treatment actuations



**Boehringer
Ingelheim**



Instruction Video

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Aservo® Equihaler®

30 mg/ml

inhalation solution for horses
ciclesonide



Marketing authorisation holder

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release

Fareva Amboise
Zone industrielle
29 Route des Industries
37530 Pocé-sur-Cisse
France

Active substance and other ingredients

Ciclesonide 30 mg/ml
Ethanol anhydrous 691.6 mg/ml

Clear, colourless to yellowish solution.

Indication

For the treatment of horses with moderate to severe clinical signs of equine asthma.

Contraindications

Do not use in known cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.

Adverse reactions

Mild nasal discharge was commonly observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Target species

Horse

Dosage, routes and method of administration

Inhalation use.

The number of actuations administered is identical for all horses independent of their body weight. The total treatment duration is 10 days.

Day 1 to 5:

8 actuations (corresponding to 2,744 µg ciclesonide) administered twice daily approximately 12 h apart.

Day 6 to 10:

12 actuations (corresponding to 4,116 µg ciclesonide) administered once daily approximately 24 h apart.

Treatment schedule for use as follows:

| Total treatment duration is 10 days | |
|---|---|
| Treatment days 1 to 5 | Treatment days 6 to 10 |
| 8 actuations morning and evening approximately 12 h apart | 12 actuations morning or evening approximately 24 h apart |

If an administration is missed or incomplete, administer the next treatment as described above.

An improvement in clinical signs is usually evident within the treatment period. The horse's clinical condition should be reassessed after this period before any further treatment is proposed.

Advice on correct administration

The **Instructions for handling and use of the Aservo® Equihaler®** is provided in section „Other information“ of this leaflet.

Withdrawal period

Meat and offal: 3 days.

Not authorised for use in animals producing milk for human consumption.

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not refrigerate or freeze.

Shelf life after first activation: 12 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label after EXP.

Special warnings

Special precautions for use in animals

The product has not been tested in horses weighing less than 100 kg body weight.

Special care should be taken when administering the product.

To ensure a safe and efficacious administration, the breath indicator (respiration indicator) located in the chamber wall of the nostril adapter, which indicates the breathing phase by deflection, needs to be observed: when the horse inhales, the breath indicator curves inwards.

During exhalation, the breath indicator curves outwards. The spray should be released when the breath indicator starts curving into the chamber.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Follow the instructions in the leaflet closely.

People with known hypersensitivity to ciclesonide or any of the excipients should avoid contact with the veterinary medicinal product.

In case of accidental inhalation, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation

The safety of the veterinary medicinal product during pregnancy or lactation has not been tested and thus, should be used according to the benefit/risk assessment of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Concomitant use of clenbuterol in a field study in horses with moderate to severe clinical signs of equine asthma did not indicate any safety concerns.

In case of other diseases, some horses may need to be given non-steroidal anti-inflammatory drugs (NSAIDs) which can be done concomitantly for a short period of time. Prolonged concomitant administration of NSAIDs should be avoided.

Overdose (symptoms, emergency procedures, antidotes)

In case of overdose, symptomatic treatment should be initiated.

Disposal of unused product or waste materials

Medicines should not be disposed via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved

MM YYYY

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

Other information

Pack size: 1 Aservo® Equihaler® with a pre-inserted cartridge which contains inhalation solution for 140 treatment actuations.

Instructions for handling and use of the Aservo® EquiHaler®

Please read the following instructions carefully prior to first use of the Aservo® EquiHaler® which can be also found when using the URL info.equi-haler.com or the enclosed QR code. The Aservo EquiHaler is an inhaler for horses. It contains sufficient inhalation solution for the entire period of the 10 days treatment. Thus, there is no need to refill the inhaler.



Introduction to the Aservo® EquiHaler®

The Aservo® EquiHaler® is for **left hand** use only. While holding the Aservo® EquiHaler® with your left hand, you hold and control your horse with your right hand.



Remove the Aservo® EquiHaler® from the outer carton.



Familiarise yourself with the inhaler. It consists of:

- A** Nostril adapter
- B** Breath indicator
- C** Air inlet
- D** Handle
- E** Prime and release lever
- F** Piercing element with fill indicator

In the following chapters, **activation**, **priming**, **administration**, **cleaning**, and **storage** of the Aservo® EquiHaler® is described in detail.

Activation of the Aservo® EquiHaler®

Activation of the Aservo® EquiHaler® has to be performed **only once prior to first use**.



To activate the Aservo® EquiHaler®, the piercing element **F** needs to be inserted into the handle of the inhaler without pressing the lever **E**.

Put your right hand under the dark grey piercing element **F** ...



... and push the piercing element **F** up completely into the handle **D** until you will hear a click.

In the final position, the piercing element will disappear entirely in the handle **D** and is no longer visible.

The Aservo® EquiHaler® is now activated, but not ready to use.

Priming

Priming is required to ensure accurate initial dosing. Priming is performed **only once** and comprises three (3) actuations. The spray will be fully visible after the third actuation.

When pressing the lever **E** of the Aservo® EquiHaler® for the first time, the lower part of the piercing element with the fill indicator **F** will become visible again. **Do not push the piercing element back up into the device.**

Actuation

Each **actuation** consists of the following steps (pictures 5 to 8):



Hold the Aservo® EquiHaler® upright in your left hand.



Press the prime and release lever **E** until it touches the handle and a click can be heard.

Release the lever **E** allowing it to slide back into its starting position.

Actuation



The fill indicator in the piercing element will now turn red.



Press the prime and release lever **E** **again** with light pressure only until you hear an audible click. Let the lever slide back into its starting position. The spray will be released into the nostril adapter **A**.

The fill indicator now displays the filling level in %.

Please note:

Should the piercing element be accidentally pushed completely into the handle again, it will automatically slide into the correct position when the Aservo® EquiHaler® is actuated the next time.

Administration

The nostril adapter should remain in the nostril during the entire administration of the 8 or 12 actuations. If the nostril adapter slides out of the nostril during administration please re-insert into the nostril again.



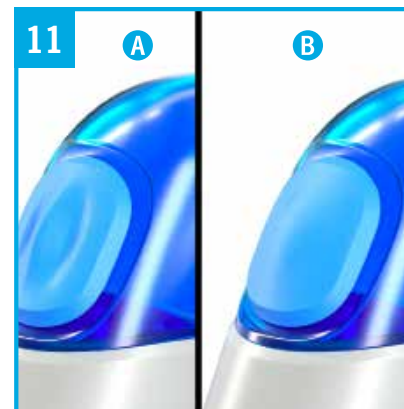
Hold the Aservo® EquiHaler® in your **left** hand. Make sure that the air inlet **C** is not obstructed.

Stand on the **left** side of the horse so that the horse's head is next to your right shoulder.



Insert the nostril adapter **A** carefully into the horse's left nostril, and gently rotate the inhaler into an upright position. Assure that the nostril adaptor is inserted in the nasal cavity.

Administration



Observe the movement of the breath indicator **B**:

When the horse inhales, the breath indicator curves inwards (*picture A*). When the horse exhales, the breath indicator curves outwards (*picture B*).

The optimum time for release is at the **beginning** of the horse's inspiration when the breath indicator **B** begins to curve inwards.

Please note: In order for the breath indicator to demonstrate when the horse inhales or exhales, the nostril adapter **A** must be correctly placed in the nostril and should fit tightly.



Every actuation should be performed following the steps explained in pictures 6, 7, and 8.

Administer the correct number of actuations as described in section "Dosage, routes and method of administration" of the leaflet above.

Fill indicator

The **fill indicator** shows the percentage of actuations available in the inhaler. The fill indicator should display 100% prior to first use, i.e. after the Aservo® EquiHaler® is primed.

 0·10·20·30·40·50·60·70·80·90·100%

The display of the fill indicator only moves after several actuations. When the display has reached the position **0%** the product should no longer be used. However, the prime and release lever will still work.

Cleaning of the Aservo® EquiHaler®

After each use and **before cleaning**, check that the fill indicator is blue/white. If it is red, press the prime and release lever **E** until the click is heard. This will assure that you do not accidentally release any spray. To avoid inhalation, hold the inhaler away from your body.

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After use, twist and lift nostril adapter **A** from the handle **D**.

Store the handle in a clean and dry place.

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Rinse the nostril adapter **A** **only** in clean running water. Do not use any brushes or cleaning products.

The nostril adapter is not suitable for the dishwasher.



Cleaning of the Aservo® EquiHaler®

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The nostril adapter **A** must be **air dried in an upright position** for at least 4 hours.

Do not rub dry or heat.
Do not use technical equipment such as hair dryer, microwave, or heating element.

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Once the nostril adapter **A** is dry it should be reattached to the handle **D** by pushing it down firmly and twisting slightly until it slides into its place.

The nostril adapter **A** only locks in one position and should fit tightly to the handle.

The Aservo® EquiHaler® is now ready for the next use.

Storage of the Aservo® EquiHaler®

Do not store the Aservo® EquiHaler® (handle and nostril adapter) above 30°C.
Do not refrigerate or freeze. Store the inhaler with the fill indicator on blue/white only; do not store with the fill indicator on red.

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