ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aservo EquiHaler 343 micrograms/actuation inhalation solution for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation (ex nostril adapter) contains:

Active substance:
Ciclesonide 343 micrograms

Excipients:
Ethanol: 8.4 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation solution.
Clear, colourless to yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horse

4.2 Indications for use, specifying the target species

For the alleviation of clinical signs of severe equine asthma (formerly known as Recurrent Airway Obstruction– (RAO), Summer Pasture Associated Recurrent Airway Obstruction – (SPA-RAO)).

4.3 Contraindications

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

4.4 Special warnings for each target species

Special care should be taken when administering the veterinary medicinal product. To ensure an efficacious administration, the breath indicator in the chamber wall of the nostril adapter needs to be observed: when the horse inhales, the membrane of the breath indicator curves inwards. During exhalation, the membrane of the breath indicator curves outwards. The spray should be released at the beginning of inhalation, i.e. when the breath indicator starts curving into the chamber. If the movement of the breath indicator cannot be observed, assure the correct positioning of the nostril adapter. If movement of the breath indicator is still not visible or the movement is too rapid, the product should not be administered.
Efficacy of the product has not been established in horses with acute exacerbations (<14 days duration) of clinical signs.

4.5 Special precautions for use

Special precautions for use in animals
Safety of the veterinary medicinal product has not been established in horses weighing less than 200 kg body weight, or in foals.

The prescribing veterinarian should assess if the horse has a temperament suitable for a safe and efficacious administration of the Aservo EquiHaler in agreement with good veterinary practice. Horses might not adapt to an easy and safe application of the Aservo EquiHaler within a couple of days. In such cases, an alternative treatment should be considered.

The onset of clinical improvement may take several days. The use of concomitant medication (such as bronchodilators) and environmental control may need to be considered in cases of severe clinical signs of respiratory obstruction, at the discretion of the attending veterinarian (see also section 4.8).

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Follow closely the instructions for handling and use of the Aservo EquiHaler as provided in the package leaflet section "Other Information".

Administration of the product should take place in well ventilated surroundings.

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

Inhalative or intranasal corticosteroids may cause rhinitis, nasal discomfort, nosebleed, upper respiratory tract infection and headache. An aerosol filtering mask must be worn during handling and administration. This prevents inadvertent inhalation in case of unintended release of actuations outside the nostril or without the nostril adapter.

The product 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 experiencing an adverse reaction due to accidental inhalation, and in case of eye irritation, seek medical advice and show the package leaflet or the label to the physician.

These precautions should be followed by the person administering the product and persons in close proximity to the horse's head during administration.

The safety of ciclesonide after inhalatory exposure has not been established in pregnant women. In animal studies ciclesonide has been shown to induce malformations in foetuses (cleft palate, skeletal malformations). Pregnant women should therefore not administer the product.

If the Aservo EquiHaler is visually damaged it should not be used any more.

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

4.6 Adverse reactions (frequency and seriousness)

Mild nasal discharge was commonly observed during safety and clinical studies.

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

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.
The product was shown to be teratogenic following oral administration after high doses in rabbits but not in rats.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Inhalation use.

The number of actuations to be administered is the same for all horses. 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.

The onset of clinical improvement may take several days. The 10 days treatment schedule should normally be completed. In case of any concerns related to the treatment the responsible veterinarian should be consulted.

The Aservo EquiHaler contains sufficient inhalation solution for one horse for the entire treatment duration of the 10 days and an additional amount covering priming and potential losses during administration.

Treatment schedule for use:

Treatment days 1 to 5	**Treatment days 6 to 10**
8 actuations morning **and** evening approximately 12 h apart	12 actuations once daily approximately 24 h apart

The "**Instructions for handling and use of the Aservo EquiHaler**" is provided in section "Other information" of the package leaflet.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of the veterinary medicinal product at up to the 3-fold recommended dose for 3 times the recommended treatment duration no relevant clinical signs were observed.

4.11 Withdrawal period(s)

Meat and offal: 18 days
Not authorised for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Respiratory system, other drugs for obstructive airway diseases, inhalants
ATCvet code: QR03BA08

5.1 Pharmacodynamic properties

Ciclesonide is a prodrug which is enzymatically converted to the pharmacologically active metabolite desisobutyryl-ciclesonide (des-ciclesonide) following inhalation. The glucocorticoid-receptor affinity of des-ciclesonide was tested in rats and humans and demonstrated that the glucocorticoid-receptor affinity of des-ciclesonide is up to 120 times greater than the parent compound's affinity and 12 times greater than dexamethasone's affinity. Des-ciclesonide has anti-inflammatory properties which are exerted through a wide range of inhibitory activities.

In general, cortisol levels serve as a marker for suppression of the hypothalamic-pituitary-adrenal axis by systemic action of corticosteroids which could be associated with side effects.

No statistically significant suppression of cortisol levels was observed in horses with equine asthma at the recommended dosing regimen and in healthy horses with ciclesonide treatment up to three times the dose and three times the duration.

The pivotal field trial included horses (mean age 18.5 years) with severe equine asthma characterised by the following main criteria: clinical signs >14 days duration; horses that tolerated insertion of the nostril adapter; laboured breathing at rest; weighted clinical score ≥11/23. The weighted clinical score included the following parameters: coughing, nasal discharge, nasal flaring, laboured breathing at rest, respiratory rate, tracheal sounds and abnormal lung sounds. Clinical success was defined as an improvement of at least 30% in the weighted clinical score. In total, 73.4% of the ciclesonide group and 43.2% of the placebo group demonstrated treatment success, and the difference between the groups was statistically significant.

5.2 Pharmacokinetic particulars

Absorption
Ciclesonide was rapidly absorbed after inhalation with a median T_{max} of about 5 minutes after the last actuation and rapidly converted to its active metabolite des-ciclesonide as shown by concentrations at the first sampling time, i.e. 5 minutes after the last actuation.

Distribution
The volume of distribution in horses is 25.7 l/kg, indicating that ciclesonide is distributed readily into the tissues.
Following inhalative administration in horses, the absolute systemic bioavailability of ciclesonide was very low and was not higher than 5%-17%. The apparent systemic bioavailability of des-ciclesonide following administration of ciclesonide was in the range of 33.8%-59.0%. The plasma exposure for ciclesonide and des-ciclesonide in terms of C_{max} and AUC_{last} increased with the dose. A slight trend to an increase of plasma exposure higher than the dose proportionality was observed.
In-vitro protein binding of des -ciclesonide was tested in the plasma from mice, rats, rabbits, dogs and humans (mouse plasma 98.9% to 99.1%; rat plasma 97.5% to 98.0%; rabbit plasma 99.1% to 99.2%; dog plasma 97.9% to 98.0%; human plasma 98.5% to 98.8%).

Metabolism
Ciclesonide is a pro-drug that is rapidly metabolized to the major active metabolite (des-ciclesonide) after inhalation. In vitro, three metabolites were reported as major metabolites. In vivo, only des-ciclesonide occurred whereas the other two metabolites could not be confirmed.

Elimination
The mean apparent harmonic terminal half-life after single inhalation administration was approximately 3-5 hours for ciclesonide and approximately 4-5 hours for des-ciclesonide.

Elimination of ciclesonide and its active metabolite des-ciclesonide is principally via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Hydrochloric acid
Water, purified

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first activation: 12 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

One Aservo EquiHaler with a polyurethane nostril adapter contains a pre-inserted cartridge. The cartridge consists of a polyethylene/polypropylene plastic container closed with a polypropylene cap and crimped in an aluminium cylinder. The cartridge contains sufficient inhalation solution for the entire treatment duration (140 treatment actuations). The cartridge also contains an additional amount covering priming and potential losses during administration within the 10 day treatment duration. Additionally, there is residual solution which cannot be delivered with the required accuracy, and should therefore not be administered.
The cartridge cannot be removed from the Aservo EquiHaler.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any used or unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The cartridge contains residual amount of the product at the end of the course of administration. This should be taken into account at disposal of the used veterinary medicinal product.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim am Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/249/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/01/2020

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release
Fareva Amboise
Zone Industrielle
29 Route des Industries
37530 Pocé-sur-Cisse
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The Committee for Medicinal Products for Veterinary use has recommended the inclusion of ciclesonide, the active substance in Aservo EquiHaler, in table 1 of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Ciclesonide	The sum of ciclesonide and desisobutyryl-ciclesonide, measured as desisobutyryl-ciclesonide after hydrolysis of ciclesonide to desisobutyryl-ciclesonide	*Equidae*	0,6 µg/kg 4 µg/kg 0,6 µg/kg 0,6 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Corticoides / Glucocorticoides'

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required, or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:
The periodic safety update report (PSUR) cycle should consist of submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals.

This product is a new active substance administered via an integrated novel device. To address some remaining concerns regarding the acceptance of the device and the compliance of both horse owners and horses in using the final inhalation device, the applicant has committed to provide augmented pharmacovigilance reporting in a representative number of horses from the target population.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aservo EquiHaler 343 micrograms/actuation inhalation solution for horses
ciclesonide

2. STATEMENT OF ACTIVE SUBSTANCES

ciclesonide 343 micrograms/actuation

3. PHARMACEUTICAL FORM

Inhalation solution

4. PACKAGE SIZE

1 inhaler contains 140 treatment actuations

5. TARGET SPECIES

Horse

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Inhalation use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 18 days.
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Once activated use within 12 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER

EU/2/19/249/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}
QR code to be included + info.equi-haler.com

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Inhaler

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aservo EquiHaler 343 µg/actuation inhalation solution for horses
ciclesonide

2. STATEMENT OF ACTIVE SUBSTANCES

ciclesonide 343 µg/actuation

3. PHARMACEUTICAL FORM

Inhalation solution

4. PACKAGE SIZE

1 inhaler contains 140 treatment actuations.

5. TARGET SPECIES

Horse

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Inhalation use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 18 days.
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Once activated use within 12 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBER

EU/2/19/249/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Aservo EquiHaler 343 micrograms/actuation inhalation solution for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Fareva Amboise
Zone Industrielle
29 Route des Industries
37530 Pocé-sur-Cisse
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aservo EquiHaler 343 micrograms/actuation inhalation solution for horses
ciclesonide

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each actuation (ex nostril adapter) contains:

Active substance:
Ciclesonide 343 micrograms

Excipients:
Ethanol 8.4 mg

Clear, colourless to yellowish solution.

4. INDICATION

For the alleviation of clinical signs of severe equine asthma (formerly known as Recurrent Airway Obstruction– (RAO), Summer Pasture Associated Recurrent Airway Obstruction – (SPA-RAO)).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Mild nasal discharge was commonly observed during safety and clinical studies.

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.

7. TARGET SPECIES

Horse

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Inhalation use.

The number of actuations to be administered is the same for all horses. 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.

The onset of clinical improvement may take several days. The 10 days treatment schedule should normally be completed. In case of any concerns related to the treatment the responsible veterinarian should be consulted.

The Aservo EquiHaler contains sufficient inhalation solution for one horse for the entire treatment duration of the 10 days and an additional amount covering priming and potential losses during administration.

Treatment schedule for use:

Treatment days 1 to 5	**Treatment days 6 to 10**
8 actuations morning **and** evening approximately 12 h apart	12 actuations once daily approximately 24 h apart

9. ADVICE ON CORRECT ADMINISTRATION

The "**Instructions for handling and use of the Aservo EquiHaler**" is provided in section "Other information" of this leaflet.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 18 days.
Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
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.

12. SPECIAL WARNING(S)

Special warnings for each target species
Special care should be taken when administering the veterinary medicinal product. To ensure an efficacious administration, the breath indicator in the chamber wall of the nostril adapter needs to be observed: when the horse inhales, the membrane of the breath indicator curves inwards. During exhalation, the membrane of the breath indicatior curves outwards. The spray should be released at the beginning of inhalation, i.e. when the breath indicator starts curving into the chamber. If the movement of the breath indicator cannot be observed, assure the correct positioning of the nostril adapter. If movement of the breath indicator is still not visible or the movement is too rapid, the product should not be administered.
Efficacy of the product has not been established in horses with acute exacerbations (<14 days duration) of clinical signs.

Special precautions for use in animals:
Safety of the veterinary medicinal product has not been established in horses weighing less than 200 kg body weight, or in foals.

The prescribing veterinarian should assess if the horse has a temperament suitable for a safe and efficacious administration of the Aservo EquiHaler in agreement with good veterinary practice. Horses might not adapt to an easy and safe application of the Aservo EquiHaler within a couple of days. In such cases, an alternative treatment should be considered.

The onset of clinical improvement may take several days. The use of concomitant medication (such as bronchodilators) and environmental control may need to be considered in cases of severe clinical signs of respiratory obstruction, at the discretion of the attending veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Follow closely the instructions for handling and use of the Aservo EquiHaler as provided in the package leaflet section “Other Information”.

Administration of the product should take place in well ventilated surroundings.

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

Inhalative and intranasal corticosteroids may cause rhinitis, nasal discomfort, nosebleed, upper respiratory tract infection and headache. An aerosol filtering mask must be worn during handling and administration. This prevents inadvertent inhalation in case of unintended release of actuations outside the nostril or without the nostril adapter.
The product 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 experiencing an adverse reaction due to accidental inhalation, and in case of eye irritation, seek medical advice and show the package leaflet or the label to the physician.

These precautions should be followed by the person administering the product and persons in close proximity to the horse’s head during administration.

The safety of ciclesonide after inhalatory exposure has not been established in pregnant women. In animal studies ciclesonide has been shown to induce malformations in foetuses (cleft palate, skeletal malformations). Pregnant women should therefore not administer the product.

If the Aservo EquiHaler is visually damaged it should not be used any more.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.
The product was shown to be teratogenic following oral administration after high doses in rabbits but not in rats.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of clenbuterol in a field study in seven horses with severe equine asthma did not indicate any safety concerns.

Overdose (symptoms, emergency procedures, antidotes):
After administration of the veterinary medicinal product at up to the 3-fold recommended dose for 3 times the recommended treatment duration no relevant clinical signs could be observed.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.
The cartridge contains residual amount of the product at the end of the course of administration. This should be taken into account at disposal of the used veterinary medicinal product.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

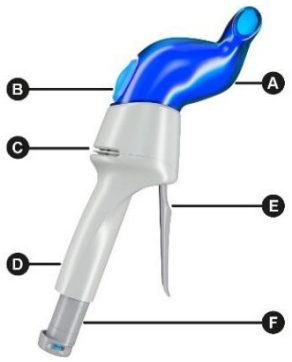
Pack size: One Aservo EquiHaler with a nostril adapter and a pre-inserted cartridge. The cartridge contains sufficient inhalation solution for the entire treatment duration (140 treatment actuations) and an additional amount covering priming and potential losses during administration within the 10 day treatment duration. Additionally there is residual solution which cannot be delivered with the required accuracy, and should therefore not be administered. The cartridge cannot be removed from the Aservo EquiHaler.

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 a product for inhalation for horses.
The Aservo EquiHaler contains sufficient inhalation solution for one horse for the entire duration of the 10 days treatment and an additional amount covering priming and potential losses during administration.

Introduction of 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.

1.		Remove the Aservo EquiHaler from the outer carton.
2.		Familiarise yourself with the Aservo EquiHaler. 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**.

3.		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** …

4.		…. 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.

An aerosol filtering mask must be worn during handling and administration. This prevents inadvertent inhalation in case of unintended release of actuations outside the nostril or without the nostril adapter.

Priming

Priming is required to ensure accurate initial dosing. Priming is performed **only once** and comprises three (3) actuations (see below). 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

The Aservo EquiHaler is **designed** for the **left hand use only and for use in the left** nostril of the horse only. While holding and operating the Aservo EquiHaler with your left hand, you hold and control your horse with your right hand.

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

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

6.		Step 1: 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.

7.		The display of the fill indicator in the piercing element is partially covered with a red flap.

8.		Step 2: 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 subsequently into the nostril adapter **A**. The fill indicator now displays the filling level in %.

Once activated the product should no longer be used after 12 days.

Please note:
Should the piercing element be accidently 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.
The Aservo EquiHaler should be administered in a well ventilated area.

9.		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** coming from a horizontal position **carefully** into the horse's left nostril, and gently rotate the Aservo Equihaler …

10.		… into an upright position. Assure that the nostril adapter is inserted in the nasal cavity.
11.		Observe the movement of the breath indicator **B**: When the horse inhales, the membrane of the breath indicator curves inwards (picture A). When the horse exhales, the membrane of 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. If the movement of the breath indicator cannot be observed, assure the correct positioning of the nostril adapter. If still no movement is visible, the product should not be administered.
12.		Every actuation should be performed following the two steps explained in pictures 6., 7., and 8. Administer the correct number of actuations as described in section “Dosage for each species, route(s) and method of administration”, see 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.

The display of the fill indicator only moves after several actuations.
After administration of the 10 days treatment schedule the display has reached the position **0%.**

The product allows an additional amount of actuations covering potential losses during administration. In this case the display of the fill indicator moves further and stops at the horse head. The inhaler must not be used after the fill indicator has reached the horse head.

Cleaning 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.

13.		After use, twist and lift nostril adapter **A** from the handle **D**. Store the handle in a clean and dry place.
14.		Rinse the nostril adapter **A only** in clean running water. Do not use any brushes or cleaning products. The handle can be carefully wiped with a moist cloth. The Aservo EquiHaler is not suitable for the dishwasher. 
15.		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 a hair dryer, microwave, or heating element.
16.		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. Gently pulling up on the nostril adapter after attaching to the handle should reveal the nostril adapter is firmly attached. The Aservo EquiHaler is now ready for the next use.

Storage of the Aservo EquiHaler

This veterinary medicinal product does not require any special storage conditions.
Do not store the Aservo EquiHaler if the fill indicator is partially covered with a red flap.