8 November 2019
EMA/CVMP/573530/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Aservo EquiHaler

International non-proprietary name (INN): ciclesonide

On 7 November 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Aservo EquiHaler, inhalation solution, intended for horses. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Aservo EquiHaler is a glucocorticoid medicinal product containing ciclesonide (ATCvet code QR03BA08) as active substance, and is a pro-drug, which following inhalation is converted into the active metabolite, desisobutyryl-ciclesonide (des-CIC) in the airways. Des-ciclesonide has anti-inflammatory properties which are exerted through a wide range of inhibitory activities.

The benefits of Aservo EquiHaler are its efficacy in the alleviation of clinical signs associated with chronic severe equine asthma. The most common side effects are mild nasal discharge.

The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

The full indication is: 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)).

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Aservo EquiHaler and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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