Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Aservo EquiHaler 343 micrograms/actuation Inhalation Solution for Horses

Vm 04491/5003

•	31 July 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	16 January 2023	Updates to sections 4.5 of the SPC.
•	27 April 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 March 2022	Change to packaging of the finished product.
•	14 October 2021	Changes to the labelling and package leaflet.
•	13 July 2021	Change to in-process limits applied during the manufacture of the finished product.
•	07 July 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Deletion of a supplier of packaging components or devices.
•	25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.