



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.