Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovalto Respi Intranasal, Nasal Spray, Lyophilisate and Solvent for Suspension

Vm 08327/5006

•	07 July 2023	Removal of two bovine serum suppliers. Updating the CEPs of two bovine serum suppliers.
•	26 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	30 December 2022	To add a new presentation. This new presentation includes a 3ml glass vial containing 1 ml of lyophilizate and a 3ml glass vial containing 2 ml of diluent. Update to the GB National SPC/QRD template.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 September 2021	Change in the number of units (e.g. tablets*, ampoules*, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	25 June 2021	Renewal – UK as CMS.
•	05 June 2020	Change in the invented name of the veterinary medicinal product from Bovalto Respi Intranasal, Nasal Spray, Lyophilisate and Solvent for Suspension to Bovalto Respi 2 Nasal Spray, Lyophilisate and Solvent for Suspension in DK , NO, and SE.
•	13 December 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 December 2018	Changes to the labelling and package leaflet
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.