



Post Authorisation Assessments

Bovalto Respi 4 Suspension for Injection

Vm 08327/5011

•	11 August 2023	Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
•	26 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	13 January 2022	Minor change in the manufacturing process of an immediate release oral solutions.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 April 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	28 April 2021	Deletion of Ph. Eur. TSE certificates of suitability for a starting material (used in manufacturing process of active).
•	11 June 2020	Renewal - UK as CMS.
•	16 December 2019	Repeat Use application to add 2 new member states.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 May 2019	Update to the dossier due to new data.
•	05 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.
•	10 January 2018	Change in the SPC, labelling or package leaflet due to new data. Change in the product name from Bovalto Respi 4 Suspension for Injection for Cattle to Bovalto Respi 4 Suspension for Injection.
•	04 August 2017	Changes to the labelling or package leaflet.
•	02 March 2017	Increase in the shelf-life of the finished product as packaged for sale to 2 years.
•	06 December 2016	Change in any part of the packaging material not in contact with the finished product formulation that does not affect the product information.
•	08 August 2016	Change in the suppliers of a starting material
•	06 July 2016	Submission of a new Ph. Eur. TSE certificate of

		suitability from a new manufacturer
--	--	-------------------------------------