



Post Authorisation Assessments

Bovalto Respi 4 Suspension for Injection

Vm 08327/5011

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| • | 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 |

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| | | suitability from a new manufacturer |
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