Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis INtranasal RSP Live, Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle

Vm 06376/3025

10 January 2025	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
27 June 2024	Changes to the multidose presentation of the finished product; to delete the final container/immediate pack of the finished product: 20 ml glass container, resulting in the deletion of the 25 dose and 50 dose pack sizes. Fine tuning of presentations in the SPC-PL: Provide the lyophilisate and solvent for the existing 10 dose not only in 1 cardboard box but also in separate cardboard boxes. Remove the 5 x 10 doses presentation. Provide the lyophilisate and solvent for the existing 20 dose not only in separate cardboard boxes but also in 1 cardboard box.
27 June 2024	Introduction of associated non-mixed use with Bovilis Nasalgen-C. Use of Bovilis INtranasal RSP Live during pregnancy. One-off alignment of the product information with version 9.0* of the QRD templates.
26 February 2024	To mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin.
17 November 2023	To add tangential flow (TF) filtration perfusion as an optional method for BRSV jencine-2013 antigen production. To optimise the thawing process of stored BRSV jencine-2013 antigen.
15 June 2023	Unlimited renewal
31 August 2022	Change to the minimum age for administration. Change to the maximum PI3 titre.
27 April 2021	Change in the number of units (20 dose presentation) in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units (25 dose presentation) in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units (50 dose presentation) in

	a pack within the range of the currently approved pack sizes of the finished product.
14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
27 July 2020	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years. Increase in the shelf-life of the finished product, from 18 month to 2 years.