



Post Authorisation Assessments

Bovilis INtranasal RSP Live, Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle Vm 01708/3034

•	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.