



Post Authorisation Assessments

Rispoval RS + Pi3 IntraNasal Vm 42058/4130

•	16 February 2023	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin powder.
•	16 November 2022	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin.
•	03 September 2020	Deletion of a specification parameter of the finished product.
•	19 August 2020	Change of a test procedure for the finished product.
•	10 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 February 2018	Change in RMS from UK to FR.
•	09 February 2017	Tightening of specification limits of the finished product.
•	08 December 2016	Change of MAH address in France, Czech Republic and Slovakia.
•	12 October 2016	Editorial changes to the SPC including a qualifier on the use during pregnancy that the safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. Change in the vial size of the 25 dose presentation. Change in the SPC, labelling or package leaflet due to new data.
•	24 September 2015	Renewal – UK as RMS.
•	05 May 2015	Change in the QPPV contact details.
•	16 January 2015	Change in pack size of the finished product.
•	10 October 2013	Variation to change the name and address of the Marketing Authorisation Holder.
•	31 July 2013	Grouped variation to transfer the Marketing Authorisation Holder and distributor.
•	09 April 2013	Repeat Use procedure.
•	12 October 2012	Introduction of a new pharmacovigilance system.
•	06 June 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	17 October 2011	Renewal.
•	23 June 2011	Change in address of Marketing Authorisation Holder.
•	08 April 2011	Change in address of Marketing Authorisation Holder.

•	10 November 2010	Changes in the manufacturing process of the active substance.
•	23 June 2010	Addition of a dosage presentation.
•	16 December 2009	Changes to the SPC.
•	22 July 2009	Addition of suppliers of components from BSE-free countries.
•	29 October 2008	Addition of storage period for freeze-dried antigen component. Refer to SPC.
•	26 June 2008	Correction or simple text layout changes to SPC/product literature.
•	18 June 2008	Change to the test methods (product).