Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Rabisin
Vm 08327/4150

•	31 October 2023	Update to the description of starting materials of biological origin.
•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	23 March 2021	Changes to the labelling and package leaflet.
•	15 February 2021	Deletion of manufacturing site for the finished product.
•	14 January 2021	Deletion of manufacturing site for an active substance.
•	26 November 2020	Change in the name of the manufacturer of the finished product.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	13 May 2020	Changes in the manufacturing process of the active substance.
•	07 May 2020	Change in description and composition of the final product. Change in the specification parameters and/or limits of the finished product.
•	May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	29 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	08 March 2018	Deletion of a non-significant specification parameter of the finished product. Change of a test procedure for the finished product.
•	31 October 2017	Replacement of a test procedure for the active substance.
•	14 January 2013	Variation to make a minor change to the manufacturing process of the Active Substance.

•	02 May 2012	Variation to change the SPC/Labels following changes to the Pet Passport.
•	13 January 2012	Variation to declare that the Active Substance used complies with the European Pharmacopeia.
•	22 December 2011	Variation to update the end of shelf life specification.
•	08 September 2010	Variation to remove a preservative from the manufacturing process.
•	23 March 2010	Addition of an Active Substance Manufacturer.
•	10 November 2009	Renewal.
•	04 March 2009	Alignment Variation.