Veterinary Medicines Directorate

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

Post Authorisation Assessments

Cryomarex Rispens

Vm 08327/4104

•	30 October 2023	Update to the description of starting materials of biological origin.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	02 March 2022	Change in the manufacturer of a starting material used in the manufacturing of the active.
•	25 January 2022	Updates to the Quality section of the product dossier.
•	22 December 2021	Change to in-process tests or limits applied during the manufacture of the finished product
•	05 May 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the 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.
•	16 June 2020	Deletion of manufacturing site for an active substance.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	08 April 2020	To delete the cryoscopic depression test from the stability studies following data submitted at T30 months.
•	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.
•	12 April 2018	Change of a test procedure for the finished product.
•	03 April 2018	Minor change in the manufacturing process of the active substance.
•	24 November 2017	Changes in the manufacturing process of the active substance.
•	06 February 2014	Deletion of a manufacturing site and addition of a manufacturer of the finished product.
•	08 July 2009	Change of composition
•	31 March 2009	Renewal
•	05 February 2009	Change of shelf life from 18 months to 37 months
•	31 July 2008	Implementation of Ph. Eur. Chapter 2.6.25

•	29 July 2008	Harmonisation of the SPC
•	08 March 2007	Change of specification of an excipient
•	19 October 2005	Change of address of manufacturer of the active substance
•	03 February 2005	Renewal
•	09 October 2003	Changes to ingredient specification Change of manufacturing site of assembly
•	31 August 2000	Change of manufacturing site of the dosage form
•	14 December 1999	Renewal
•	09 October 1998	Change of MAH
•	20 November 1995	Change of in-use shelf life