



Post Authorisation Assessments

Chronogest CR, 20 mg Controlled Release Vaginal Sponge for Sheep Vm 01708/3019

•	10 January 2024	One-off alignment of the product information with version 9.0 of the QRD template.
•	21 November 2023	Deletion of a site of manufacture, packaging, batch control, and batch release testing of the finished product.
•	04 July 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process.
•	25 January 2023	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance, a starting material, or an intermediate or reagent used in the manufacturing process of the active substance.
•	24 January 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Changes in the manufacturing process of the active substance.
•	13 January 2023	Change in the specification parameters of the active substance.
•	07 July 2022	Change in the specification parameters of the active substance.
•	28 February 2022	Changes to a test procedure (including replacement or addition) for the active substance.
•	01 December 2021	Change in the name of a manufacturer used in the manufacture of the active substance. Change to an approved stability protocol. Minor change to the restricted part of an Active Substance Master File.
•	01 July 2021	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
•	19 March 2021	Minor change in the manufacturing process of the finished product.
•	08 January 2020	Minor changes to an approved test procedure of the finished product.
•	17 July 2020	Change of MAH from Intervet International BV represented by: Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	10 June 2020	Minor change to the restricted part of an Active Substance Master File.

•	31 August 2016	Change in the name of the manufacturer of the finished product. Deletion of manufacturing site for the finished product.
•	26 August 2014	Change in immediate packaging of the finished product.
•	12 November 2013	Deletion of a manufacturing site.
•	07 May 2013	Change in re-test period of the active substance
•	21 May 2012	Change of shelf life from 60 months to 36 months
•	15 April 2010	Change to in-process test applied during the manufacture of the finished product
•	29 May 2009	Renewal Addition of a manufacturer of the active substance
•	09 February 2009	Change of specification of the active substance
•	19 January 2009	Minor change in the manufacturing process of the active substance
•	09 April 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	12 March 2008	Change of name of a manufacturer of the active substance
•	16 November 2007	Addition of a manufacturing site for part of the manufacturing process