Veterinary Medicines Directorate

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Post Authorisation Assessments

Orbenin Extra Dry Cow 600 mg Intramammary Suspension

Vm 42058/4089

•	03 April 2024	Deletion of a manufacturing site for an active substance. Deletion of an obsolete specification parameter of the active substance.
•	July 2022	Deletion of a test procedure for the finished product. Deletion of a test procedure for the finished product. Deletion of a test procedure for the finished product. Tightening in the specification limits of the finished product. Addition of a new specification parameter and corresponding test method. Change in the batch size of the finished product.
•	04 September 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.
•	23 July 2018	Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	31 August 2017	Deletion of manufacturing site for an active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	09 November 2016	Change in the name of the manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	22 March 2016	Deletion of two manufacturing sites of the active substance.
•	26 June 2014	Change to the Marketing Authorisation Holder and distributor details.
•	10 October 2010	Addition of a manufacturer of the active substance.
•	23 July 2009	Change in the name of the manufacturer of the finished product.
•	12 December 2007	Addition of a manufacturer of the active substance.
•	26 July 2007	Changes to the SPC and product literature to being in line with new legislation. Change in legal category from POM to POM-V.
•	26 January 2007	Renewal.
•	17 May 2006	Addition of indications.
•	24 June 2005	Addition of a distributor.

•	23 February 2004	Change in test procedure of the finished product.
•	27 February 2003	Change in the name of the assembler of finished product.
•	06 September 2002	Change in presentation and container.
•	05 December 1998	Renewal.
•	30 January 2001	Update Licence Particulars.
•	20 November 2000	Change to withdrawal period.
•	16 February 1998	Change of pack size.
•	09 April 1997	Addition of a manufacturer of dosage form and assembler of finished product.
•	27 February 1997	Change of MA holder.
•	15 September 1995	Change in the manufacturer of the active substance.