



Post Authorisation Assessments

Orbenin Dry Cow 500 mg Intramammary Suspension Vm 42058/4088

•	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 November 2010	Addition of a manufacturer of the active substance.
•	23 July 2009	Change in the name of the manufacturer of the finished product.
•	23 January 2008	Changes to the SPC and product literature to bring in line with new legislation. Change in legal category from POM to POM-V
•	12 December 2007	Addition of a manufacturer of the active substance.
•	14 March 2007	Increase in withdrawal period.
•	14 March 2007	Renewal.
•	28 June 2005	Additional distributors.
•	16 January 2004	Change in product container shape.
•	27 February 2003	Change in the name of the assembler of the finished product.
•	30 September 2002	Approval of mock-ups.
•	30 January 2001	Approval of mock-ups.
•	03 October 2000	Change to withdrawal period.
•	06 July 1999	Renewal.
•	16 April 1998	Variation concerning the non-sterile container.

