Veterinary Medicines Directorate

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Post Authorisation Assessments

Orbenin L.A. 200 mg Intramammary Suspension

•	09 December 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	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.
•	05 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 April 2017	Change of specification of a former non Pharmacopoeial excipient starting material to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State
•	10 September 2015	Change to withdrawal period from 84 hours to 96 hours.
•	26 June 2014	Change to the Marketing Authorisation Holder and distributor details.
•	23 July 2009	Change in the name of the manufacturer of the finished product.
•	03 October 2007	Change in the SPC and product literature to bring into line with new legislation. Change of legal category from POM to POM-V.
•	22 June 2006	Change in the manufacturing process of the active substance.
•	26 January 2006	Renewal.
•	15 July 2005	Change of distributor.
•	07 January 2005	Change of name of manufacturer of active substance.
•	18 November 2004	Renewal.
•	16 January 2004	Change in the product container shape.
•	27 February 2003	Change in the name of an assembler of the finished product.
•	15 March 2002	Change to comply with Pharmacopoeia.
•	08 December 2000	Change in manufacturer of the active substance.
•	03 November 1997	Renewal.