Veterinary Medicines Directorate

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Post Authorisation Assessments

Orbenin L.A. 200 mg Intramammary Suspension

Vm 42058/5165

23 April 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
28 March 2025	Deletion of a manufacturing site for an active substance.
14 November 2024	Change in legal entity of MA holder for UK(NI) from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin, Ireland.
02 May 2023	Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product. Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of the finished product: – tightening of specification limits.
28 April 2023	Change in test procedure for the finished product: - Other changes to a test procedure (including replacement or addition). Change in test procedure for the finished product: - Other changes to a test procedure (including replacement or addition). Change in test procedure for the finished product: - Other changes to a test procedure (including replacement or addition). 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. Change in the specification parameters and/or limits of the finished product: - Other changes. Change in the specification parameters and/or limits of the finished product: - Other changes. Change in the batch size (including batch size ranges) of the finished product: - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes.
29 March 2023	Change in specification parameters and/or limits of a measuring or administration device: - Other changes.

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.