Veterinary Medicines Directorate

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Post Authorisation Assessments

Orbenin Ophthalmic Ointment 16.67% w/w Eye Ointment

Vm 60021/3090

20 April 2026	Minor changes to an approved test procedure for the finished product.
17 April 2026	Addition of an alternative secondary packaging for the active substance.
20 May 2025	Change of Marketing Authorisation Holder 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, Dublin 18, D18 T3Y1, Ireland.
20 October 2024	Addition of a new specification parameter to the active substance specification with its corresponding test method. Addition of a new specification parameter to the active substance specification with its corresponding test method. Substantial changes in the updated version of the ASMF by Bioquim.
08 April 2024	Deletion of a manufacturing site for an active substance. Deletion of an obsolete specification parameter of the active substance.
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.
22nd March 2016	Deletion of two manufacturing sites of the active substance.
12th February 2014	Change in Distributor Details and Legal Entity.
2nd November 2010	Addition of a site of manufacture of active substance.
23rd July 2009	Change in the name of the manufacturer of finished product.
12th December 2007	Addition of a site of manufacturer of active substance.
24th October 2007	Changes to the SPC and product literature to bring in line with new legislation.
24th October 2007	Change in legal category from POM to POM-V.
14th June 2006	Renewal

25th July 2005	Addition of distributors.
16th January 2004	Change in the shape of the container.
27th February 2003	Change in the name of a site of assembly.
29th November 2000	Renewal
11th November 1999	Renewal
30th March 1999	Change regarding sterile container.
25th March 1999	Change to manufacturing site of dosage form
27th September 1995	Change to manufacturer of active substance.