



Post Authorisation Assessments

Orbenin Ophthalmic Ointment 16.67% w/w Eye Ointment Vm 42058/4091

•	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 nd March 2016	Deletion of two manufacturing sites of the active substance.
•	12 th February 2014	Change in Distributor Details and Legal Entity.
•	2 nd November 2010	Addition of a site of manufacture of active substance.
•	23 rd July 2009	Change in the name of the manufacturer of finished product.
•	12 th December 2007	Addition of a site of manufacturer of active substance.
•	24 th October 2007	Changes to the SPC and product literature to bring in line with new legislation.
•	24 th October 2007	Change in legal category from POM to POM-V.
•	14 th June 2006	Renewal
•	25 th July 2005	Addition of distributors.
•	16 th January 2004	Change in the shape of the container.
•	27 th February 2003	Change in the name of a site of assembly.
•	29 th November 2000	Renewal
•	11 th November 1999	Renewal
•	30 th March 1999	Change regarding sterile container.
•	25 th March 1999	Change to manufacturing site of dosage form
•	27 th September 1995	Change to manufacturer of active substance.