



Post Authorisation Assessments

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

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|---|---------------------------------|---|
| • | 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. |
| • | 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. |

