



Post Authorisation Assessments

Neopen Suspension for Injection

Vm 06376/4082

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| 10 December 2024 | Change in legal entity from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes MK7 7AJ to Intervet International B.V., Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands. |
| 31 July 2023 | Change in immediate packaging of the finished product. |
| 09 June 2021 | Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited. |
| 22 February 2021 | Minor change to the restricted part of an Active Substance Master File. |
| 03 June 2020 | Changes in the manufacturing process of the finished product. |
| 17 October 2019 | Addition of a manufacturer responsible for batch release including batch control/testing. Minor adjustments of the quantitative composition of the finished product with respect to excipients. Change in control of the finished product. Minor change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Replacement of an excipient with a comparable excipient. Addition of a manufacturing site of the finished product. Change in type of container for the finished product. Addition of a manufacturer of the active substance or addition of a site of manufacture. |
| 06 March 2019 | Deletion of a manufacturing site for active substances. |
| 21 September 2017 | Change in the specification limits of the finished product |
| 22 June 2016 | Deletion of a manufacturer for the finished product. |
| 19 April 2016 | Submission of a new or updated Ph. Eur. certificate of suitability |
| 08 May 2013 | Submission of an updated Ph. Eur. Certificate of Suitability for an active substance |
| 22 February 2013 | Submission of an updated Ph. Eur. Certificate of Suitability for an active substance |
| 04 October 2011 | Submission of an updated Ph. Eur. Certificate of Suitability for an active substance |
| 06 April 2011 | Addition of a manufacturer of an active substance |
| 21 July 2011 | Submission of an updated Ph. Eur. Certificate of Suitability for an active substance |
| 11 June 2008 | Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation |
| 25 October 2007 | Addition of a manufacturer of an active substance |

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| 13 September 2007 | Changes to the specification of the finished product |
| 01 May 2007 | Renewal |
| 21 February 2007 | Change of manufacturing site for the finished product Change of manufacturer of an active substance |
| 31 January 2007 | Change of distributor |
| 03 November 2005 | Change of distributor |
| 30 September 2005 | Renewal |
| 10 October 2003 | Renewal |
| 24 August 2001 | Change of distributor |
| 23 June 2000 | Update of licence particulars |
| 19 January 2000 | Change to formulation |
| 27 November 1997 | Change to type of sterile containers |
| 26 September 1997 | Change of product name from 'Neomycin Penicillin' to 'Neopen' |