Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Neopen Suspension for Injection

Vm 01708/4204

•	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

•	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’