



Post Authorisation Assessments

Gallimune 302 ND + IB + EDS Emulsion for Injection Vm 08327/3010

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| • | 25 March 2024 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| • | 22 November 2023 | One-off alignment of the product information with version 9.0* of the QRD templates. |
| • | 11 April 2023 | To replace the current PCR method for the chlamydia purity test of a starting material by another in-house PCR method. |
| • | 03 March 2023 | Addition of a secondary packaging site. |
| • | 24 January 2023 | Replacement of the currently subcontracted PCR method for the chlamydia purity test of duck embryo cells by an in-house PCR method. |
| • | 14 December 2022 | Additional secondary packaging site for the finished product. |
| • | 06 September 2022 | Changes in the manufacturing process of the active substance. |
| • | 04 July 2022 | Correction of mistakes and editorial change in the description of the manufacturing process of active substance. |
| • | 22 October 2021 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 22 October 2021 | Review and subsequent adjustment of a manufacturing process. |
| • | 02 July 2021 | Change in the specification parameters and/or limits of the immediate packaging of the finished product. |
| • | 19 March 2021 | Minor changes to an approved test procedure of the finished product |
| • | 15 February 2021 | Deletion of manufacturing site for the finished product. |
| • | 14 January 2021 | Deletion of manufacturing site for an active substance. |
| • | 14 August 2020 | Changes in the manufacturing process of the finished product. |
| • | 22 July 2020 | Change in the name of a manufacturer of the active substance. |
| • | 18 June 2020 | Change in the name of the manufacturer of the finished product. |
| • | 27 May 2020 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| • | 05 November 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |

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| • | 16 November 2018 | Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom. |
| • | 28 June 2018 | Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product. |
| • | 05 June 2017 | Changes to a test procedure (including replacement * or addition*) for a reagent used in the manufacturing process of the active substance. |
| • | 07 November 2016 | Addition of a manufacturing site of the finished product |
| • | 21 March 2014 | Change in the name and/or address of the marketing authorisation holder |
| • | 13 January 2014 | Change in the name and/or address of the marketing authorisation holder |
| • | 05 July 2013 | Update to Part II of the dossier |
| • | 06 March 2013 | Changes to comply with Ph. Eur. |
| • | 06 July 2012 | Deletion of a manufacturing site of an active substance |
| • | 23 November 2010 | Minor change of manufacturing process of an active substance |
| • | 09 July 2009 | Renewal |
| • | 29 January 2009 | Change to shelf life of the Egg Drop Syndrome active substance from 7 months to 12 months |
| • | 17 January 2008 | Change of manufacturer of the active substances |
| • | 08 March 2007 | Change of legal category from POM to POM-V |
| • | 12 February 2007 | Addition of a manufacturer of active substances |