



Post Authorisation Assessments

Gallimune 303 ND + IB + ART

Vm 61700/5009

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| 02 December 2025 | Change in legal entity of MA holder from Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. |
| 01 November 2023 | Update to the description of starting materials of biological origin. |
| 14 April 2023 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). |
| 08 March 2023 | Addition of a secondary packaging site. |
| 10 February 2023 | The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance. |
| 20 January 2023 | Deletion of a manufacturing site of the active substance. |
| 12 December 2022 | Addition of a secondary packaging site. |
| 09 December 2022 | Deletion of a manufacturer of the active substance. |
| 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. |
| 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. |
| 10 November 2020 | Change of a test procedure for the active substance. |
| 14 October 2020 | Change in the name of a manufacturer of active substance used in the manufacture of the 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 |

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| | pharmacovigilance system as described in the DDPS. |
| 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. |
| 23 July 2018 | Replacement of a test procedure for the finished product. |
| 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. |
| 31 October 2017 | Replacement of a test procedure for 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. |
| 13 July 2009 | Addition of a manufacturing site for an active substance |
| 09 July 2009 | Renewal |
| 07 March 2007 | Joint labelling between UK and IE |
| 12 February 2007 | Addition of a manufacturer of active substances |