Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Gallimune 303 ND + IB + ART

Vm 08327/5022

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| • | 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 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 |

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|---|---|---|
| | | 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.<br>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 |