Veterinary Medicines Directorate

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

# Post Authorisation Assessments

## Hyonate 10 mg/ml Solution for Injection

Vm 08327/4272

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| • | 24 April 2023 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). |
| • | 21 June 2022 | Updates to outer carton.<br>Updates to package leaflet. |
| • | 15 June 2022 | Change in the name of a manufacturer of the finished product.<br>Change in the name of the manufacturer of the active substance. |
| • | 21 July 2021 | Deletion of manufacturing site for a finished product. |
| • | 26 April 2021 | 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. |
| • | 28 May 2020 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| • | 10 March 2020 | Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. |
| • | 07 August 2019 | Changes to the labelling and package leaflet. |
| • | 29 November 2018 | Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS. |
| • | 28 April 2017 | Minor changes to an approved test procedure of the finished product.<br>Replacement of a site where batch control/testing takes place. |
| • | 04 November 2015 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 28 July 2015 | Introduction of a new pharmacovigilance system. |
| • | 14 July 2015 | Removal of a distributor.<br>Change of MAH from Bayer plc to Merial Animal Health Limited. |
| • | 01 June 2015 | Addition of a manufacturer for secondary packaging and responsible for batch release. |
| • | 16 June 2014 | Updated mock-ups approved. |
| • | 22 February 2011 | Change of distributor |
| • | 26 May 2010 | Updates to Part II of the Dossier |
| • | 07 June 2006 | Changes to the SPC and Product Literature to bring in |

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| | | line with new legislation |
| • | 24 May 2006 | Change to specification of the active substance |
| • | 21 April 2006 | Change to specification of the finished product |
| • | 18 January 2006 | Renewal |
| • | 11 January 2006 | Addition of a new presentation – 5ml vial |
| • | 07 January 2005 | Change of address of the manufacturer of the active substance |
| • | 31 December 2004 | Change of name of the manufacturer of the dosage form |
| • | 02 December 2004 | Harmonisation of the SPC |
| • | 18 September 2003 | Change of address of the MAH |
| • | 25 April 2002 | Change of batch size of the active substance |
| • | 02 August 2001 | Renewal |
| • | 02 November 1999 | Change to specification of the finished product |
| • | 06 May 1998 | Change to specification of the finished product |
| • | 12 September 1995 | Change to safety warnings |
| • | 06 December 1993 | Change to product name |