



Post Authorisation Assessments

Hyonate 10 mg/ml Solution for Injection Vm 08327/5055

07 January 2026	Deletion of a non-significant specification parameter for an active substance.
30 April 2025	Change in the name of a manufacturer or importer of the finished product including batch release or quality control testing sites. Change in the name of a manufacturer of the active substance where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability is part of the approved dossier.
20 March 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
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. Updates to package leaflet.
15 June 2022	Change in the name of a manufacturer of the finished product. 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. 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. 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. 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 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