Veterinary Medicines Directorate

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Post Authorisation Assessments

Ivomec Injection for Pigs (Ivermectin)

•	09 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	28 August 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	22 May 2019	Minor change in the manufacturing process of the finished product.
•	07 February 2019	Change in the name of the manufacturer of the finished product.
•	02 January 2019	Change in the manufacturing process of the active substance.
•	30 October 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.
•	29 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	20 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	15 July 2014	Change to the manufacturing process of the finished product.
•	28 February 2014	Deletion of a manufacturing site.
•	03 September 2013	Addition of a batch control testing site.
•	26 June 2012	Deletion of an active substance supplier. Submission of updated EDQM certificates of suitability for two active substance suppliers.
•	27 March 2012	Change in the source of an excipient to vegetable origin.
•	02 July 2009	Decrease in withdrawal period.
•	19 December 2007	Addition of a manufacturer of the active substance.
•	19 December 2007	Addition of a manufacturer of the active substance.
•	17 December 2007	Renewal.
•	18 April 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	18 April 2007	Change of legal category from PML to POM-VPS.
•	27 February 2006	Addition of a site of finished product manufacturer, change in the manufacturing process of the finished product and addition of a batch release site.

•	27 February 2006	Addition of a second type of primary packaging.
•	16 January 2006	Change in test procedure of the finished product.
•	19 December 2005	Change to test method of the finished product.
•	20 July 2005	Update to Part IIC of the dossier.
•	26 May 2005	Update to Part IIF of the dossier.
•	26 May 2005	Update to Part IIE of the dossier.
•	26 May 2005	Update to Part IIB of the dossier.
•	19 February 2004	Renewal.
•	26 June 2003	Deletion of a manufacturer and assembler of dosage form.
•	25 October 2000	Change to Finished Product Specification.
•	27 July 2000	Change in dosage and administration.
•	03 September 1998	Renewal.
•	06 August 1998	Change of MAH.
•	29 October 1997	Change of monograph.
•	27 February 1997	Change to indications.
•	02 October 1996	Change to pharmaceutical properties.
•	27 May 1996	Additional pack sizes.