



Post Authorisation Assessments

Panomec Injection for Cattle, Sheep and Pigs (Ivermectin)

Vm 08327/4193

•	03 October 2023	Minor change in the manufacturing process of the finished product.
•	April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	10 August 2022	Change in address of manufacturer of the finished product.
•	30 December 2021	Change in the name and/or address of a manufacturer of the finished product.
•	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).
•	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.
•	05 September 2016	Changes to advice on dosing regimen and minor changes to wording of SPC.
•	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 site for batch control testing.
•	26 June 2012	Deletion of an active substance manufacturer. Submission of updated EDQM certificates of suitability from already approved active substance manufacturers.
•	27 March 2012	Change to the source of an excipient to vegetable origin.
•	13 April 2011	Addition of resistance warnings to the SPC and product literature.

•	13 January 2010	Change to cattle meat withdrawal period.
•	02 July 2009	Change to pig withdrawal period.
•	27 May 2009	Change to sheep withdrawal period.
•	19 December 2007	Addition of an active substance manufacturer.
•	19 December 2007	Addition of an active substance manufacturer.
•	10 December 2007	Renewal.
•	09 November 2007	Increase in cattle withdrawal period.
•	18 April 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	27 February 2006	Addition of a second type of primary packaging.
•	27 February 2006	Addition of a finished product manufacturer, change in the manufacturing process of the finished product and addition of a site of batch release.
•	16 January 2006	Change in test procedure of the finished product.
•	19 December 2005	Registration of an analytical method.
•	20 July 2005	Update to the Part IIC dossier.
•	26 May 2005	Update to the Part IIF dossier.
•	26 May 2005	Update to the Part IIE dossier.
•	26 May 2005	Update to the Part IIB dossier.
•	26 June 2003	Deletion of a manufacturer and assembler of dosage form.
•	11 June 2003	Deletion of a manufacturer and assembler of dosage form.
•	26 October 2000	Changes to Finished Product Specifications.
•	02 July 1999	Change to lamb dosage particulars.
•	14 December 1998	Change to name and address of MAH.
•	23 October 1996	Change to contra-indications.
•	20 September 1996	Change to made of action.
•	26 July 1996	Addition to indications.
•	25 March 1996	Change to contra-indications.