Veterinary Medicines Directorate

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

Post Authorisation Assessments

Ivomec Classic Injection for Cattle and Sheep (Ivermectin)

Vm 08327/4188

04 March 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
03 October 2023	Minor change in the manufacturing process of the finished product.
24 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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.
09 June 2016	Minor Changes to the SPC and a change to recommended dosing to give responsibility to the vet.
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.
03 September 2013	Addition of a site responsible for batch control/testing.
26 June 2012	Grouped variation concerning the: deletion of an active substance manufacturer, and the submission of an updated European Pharmacopoeia Certificates of

	Suitability for active substance manufacturers.
27 March 2012	Variation to change the source of glycerol formal to vegetable origin.
15 September 2010	Simple text changes to SPC and labelling.
24 August 2010	To remove a manufacturing, packaging, labelling, testing and release site of the finished product.
27 May 2009	Decrease of withdrawal period from 42 to 37 days for sheep.
28 January 2008	Renewal procedure.
19 December 2007	Submission of a new or updated Ph. Eur certificate of suitability.
19 December 2007	Submission of a new or updated Ph. Eur certificate of suitability.
09 November 2007	Increase of cattle withdrawal period.
25 April 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
27 February 2006	To change the primary packaging.
27 February 2006	Change in the manufacturing process and the addition of a site responsible for batch release.
16 January 2006	Change in test procedure of the finished product.
19 December 2005	Change in test procedure of the finished product.
20 July 2005	Update Part IIB of the Dossier.
26 May 2005	Update Part IIE of the Dossier.
26 May 2005	Update Part IIF of the Dossier.
26 May 2005	Update Part IIC of the Dossier.
25 October 2000	Change to the finished product.
21 July 2000	Change to the dosage particulars.
20 April 1999	Change of product name.
15 July 1998	Change of Marketing Authorisation Holder.