Veterinary Medicines Directorate

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

Post Authorisation Assessments

Ivomec Super Injection for Cattle (Ivermectin and Clorsulon)

Vm 08327/4167

04 March 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
05 October 2023	Minor change in the manufacturing process of the finished product.
05 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 the manufacturer of the finished product.
12 July 2022	Change in the manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
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.
31 July 2019	Change in shape or dimensions of the container or closure (immediate packaging).
03 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.
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.
07 November 2014	Deletion of two manufacturing sites.
29 July 2014	Change in manufacturer of a starting material used in the manufacturing process of the active substance.

14 July 2014	Change to the manufacturing process of the finished product.
13 May 2014	Change in the batch size of the active substance.
12 September 2013	Deletion of a manufacturing site of the finished product.
03 September 2013	Addition of a site for batch control testing.
26 September 2012	To replace a supplier.
26 June 2012	Deletion of a manufacturing site. Submission of an updated certificate of suitability for the active substances.
27 March 2012	Variation to change the source of glycerol formal to vegetable origin.
22 February 2011	To add resistance warnings to the SPC and product literature.
23 December 2010	Minor change to the manufacturing process.
13 January 2010	Submission made following formal advice of VMD.
29 January 2008	Renewal procedure.
19 December 2007	Submission of a new/updated certificate of suitability.
09 November 2007	Change in withdrawal period.
12 April 2007	SPC/ label changes.
19 October 2006	Change in the primary package of the finished product. Change in the test procedure for the finished product. Addition of a manufacturing site.
28 September 2006	To change the test procedure of the finished product.
22 August 2006	Addition of a manufacturing site.
22 August 2006	Addition of a manufacturing site.