

Post Authorisation Assessments

Ivomec Classic Pour-on for Cattle Vm 08327/5054

20 February 2025	Submission of an updated CEP from an already approved manufacturer for an active substance.
24 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
20 December 2022	Minor changes to an approved test procedure for active substance.
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.
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.
15 February 2017	Change in storage conditions of the finished product.
25 January 2017	Tightening of specification limits of the immediate packaging of the finished product. Change in specification parameters of the immediate packaging of the finished product.
05 September 2016	Changes to advice on dosing regimen and minor changes to wording of SPC.
22 July 2016	Updates to the SPC and PL after renewal of copycat product Molemec, namely removing 3,8,13 dosing schedule.
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.
02 June 2015	Replacement of existing dosing device for the 250ml & 1litre presentations.
09 January 2015	Change to the immediate packaging of the finished product.
26 June 2012	Deletion of a manufacturing site for an active substance. Submission of two updated Ph. Eur. Certificates of Suitability for an active substance.
06 October 2010	Addition of warnings regarding resistance to sections 4.4

	and 4.9 of the SPC and Product Literature.
18 March 2008	Renewal.
19 December 2007	Addition of two manufacturers of the active substance.
20 September 2007	Change of legal category from PML to POM-VPS. Changes to the SPC and Product Literature to bring in line with new legislation.
20 July 2007	Addition of a manufacturing, packaging and testing site. Minor change in manufacturing process of the finished product.
19 June 2007	Change of batch size of the finished product.
16 February 2006	Change of withdrawal period for Meat from Cattle from 28 days to 15 days.
12 May 2005	Updates to Part II of the Dossier.
04 February 2005	Update to Part II of the Dossier.
12 March 2004	Change to specification of the finished product.
05 September 2003	Renewal.
27 October 2000	Change to specification of the finished product.
04 November 1999	Change to safety warnings.
29 October 1998	Renewal.
12 June 1998	Change of product name from 'Ivomec Pour-on for Cattle' to 'Ivomec Classic Pour-on for Cattle'.
08 May 1998	Change of MAH.
29 January 1998	Change to specification of the finished product.
02 December 1996	Change to safety warnings.
10 October 1996	Change to safety warnings.
20 September 1996	Updates to section 5.1 of the SPC.
13 June 1996	Change to batch size. Additional indication.
31 January 1995	Addition of indication.