



Post Authorisation Assessments

Oramec Drench (Ivermectin)

Vm 08327/4191

20 February 2025	Submission of an updated CEP from an already approved manufacturer for an active substance.
12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
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.
21 March 2019	Change in the SPC, labelling and Package Leaflet of a medicinal 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.
13 June 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
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.
30 April 2015	Change in the immediate packaging of the finished product.
26 June 2012	Deletion of a manufacturer of the active substance.
26 June 2012	Submission of revised certificates of suitability for manufacturers of the active substance.
22 December 2010	Change in the shelf life of the finished product.
15 September 2010	Addition of warnings to the SPC and product literature.
21 July 2010	Change in shape of the packaging of the finished product.
29 October 2009	Change in shelf life of the finished product.
28 May 2008	Change in test procedure of the finished product.
19 December 2007	Addition of active substance manufacturers.
04 October 2007	Changes to the SPC and product literature to bring in line with new legislation.

12 June 2007	Renewal.
15 March 2007	Reduction in withdrawal period for sheep from 14 days to 6 days.
07 March 2007	Change in name of the manufacturing site of finished product.
18 December 2006	Change in the source of an excipient or reagent.
11 July 2006	Change in legal category from PML to POM VPS.
20 April 2006	Addition of a finished product manufacturing site and addition of a batch release site.
14 March 2006	Change in test procedure of the finished product.
16 February 2006	Change in the batch size of the finished product.
20 July 2005	Change in test procedure of the finished product.
22 March 2005	Update of the Part II dossier.
27 January 2005	Update of the Part II dossier.
25 November 2004	Change in target species.
11 March 2004	Change in specification of the finished product.
10 January 2002	Change to finished product container details.
30 November 2000	Change to pack details.
27 October 2000	Change in finished product specification.
29 June 2000	Change to finished product container details.
20 June 2000	Renewal.
30 January 2000	Change to pack details.
7 August 1998	Change to MAH.
15 October 1997	Change of monograph.
26 June 1997	Change of pack sizes.