



Post Authorisation Assessments

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion Vm 44684/4003

18 December 2025	Submission of an updated Ph. Eur. CEP for an active substance.
11 May 2024	Minor changes:- to an approved test procedure for the finished product. (GB)
14 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
30 November 2022	Changes in the SPC, labelling or package leaflet, to sections 4.5, 4.6, 4.9 and 6, 8, 12.
03 March 2022	Change in the address of the marketing authorisation holder from AUDEVARD, 42-46 rue Médéric 92110, Clichy, France to AUDEVARD, 37-39 rue de Neuilly, 92110 Clichy, France. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
30 November 2021	Change in the address of a manufacturer of the finished product, also responsible for batch release. Submission of a new Ph. Eur. certificate of suitability for an active substance.
18 November 2020	Introduction of a new pharmacovigilance system.
24 March 2020	Changes to the labelling and/or package leaflet.
07 January 2020	Change of MAH from Eli Lilly and Company Limited, Elanco Animal Health, Lilly House, Priestley Road, Basingstoke to AUDEVARD, 42-46 rue Médéric, 92110 Clichy, France Change in distributor details to AUDEVARD, 42-46 rue Médéric, 92110 Clichy, France. Introduction of a new pharmacovigilance system.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
22 January 2015	Changes to the labelling and package leaflet.
28 August 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
31 January 2013	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer.
09 January 2013	Replacement of a measuring device.
04 September 2012	Change of MAH.
07 March 2012	Change in distributor details.
21 June 2011	Change to composition of a packaging component.
17 May 2011	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance.
22 February 2011	Introduction of a measuring device for the 100ml pack size.
05 May 2010	Changes to the specification of the finished product.
27 April 2010	Addition of an in-use shelf life of 3 months.

24 August 2009	Harmonisation of the SPC.
16 December 2008	Change of legal category from P to POM-VPS. Changes to the SPC and Product Literature to bring in line with new legislation.
14 October 2008	Change of shelf life from 5 years to 3 years.
07 March 2008	Change of address of the MAH.
25 November 2006	Submission of a Ph. Eur. Certificate of Suitability for a manufacturer.
10 May 2006	Renewal. Change of withdrawal period for horses from 6 months to nil.
21 December 2005	Change of composition of a packaging component.
07 September 2005	Updates to Part II of the Dossier.
17 March 2005	Change of name of manufacturer and assembler of the dosage form.
23 September 2004	Changes to the SPC and Product Literature to bring in line with new legislation.
28 August 2003	Change of manufacturing site for manufacture and assembly of the dosage form..
29 May 2003	Changes to specification of the finished product.
24 August 2001	Addition of a manufacturing site for secondary assembly of the dosage form.
15 November 2000	Renewal.
07 September 1995	Change of distributor.
13 August 1995	Renewal.
07 April 1995	Change of name and address of the MAH. Change of product name.