Veterinary Medicines Directorate

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Post Authorisation Assessments

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Vm 44684/4003

•	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.