Veterinary Medicines Directorate

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Post Authorisation Assessments

Intra-Epicaine 20 mg/ml Solution for Injection for Horses

Vm 50406/3021

13 February 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
06 September 2022	Minor changes to the manufacturing process of the finished product.
22 August 2022	Change of the weight, type and thickness of the sachets in which the cleaning towels are packaged.
08 July 2022	Editorial changes to Parts 2D, 2E and 2F of the dossier.
21 April 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
30 May 2019	Deletion of manufacturing site for an active substance.
17 April 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
12 December 2017	Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product.
28 August 2015	Updates to the SPC and product literature.
02 June 2015	Change to the MAH address.
09 January 2015	Submission of a new Ph. Eur. Certificate of Suitability for the manufacturer of the active ingredient.
26 April 2013	Change to batch size of the finished product.
12 March 2013	Change of name of manufacturer of a packaging component.
04 July 2012	Change of name of manufacturer of a packaging component.
22 March 2012	Replacement of the Active Substance Master File (ASMF) with a Ph. Eur. Certificate of Suitability.
30 November 2011	Changes to the SPC and Product Literature.
14 November 2011	Removal of a manufacturer of the active substance.
26 January 2011	Change of distributor.
07 October 2009	Addition of a manufacturer of packaging components.
04 August 2009	Change of shelf life of the finished product from 2 years to 5 years.
02 June 2008	Submission of an updated Ph. Eur. Certificate of

	Suitability for the active substance.
12 March 2008	Change of pack size from 10 vials to 6 vials.
15 January 2008	Harmonisation of the SPC.
05 September 2007	Change of withdrawal period to ‘not to be used in animals intended for human consumption’.
22 March 2007	Change to specification of the finished product.
16 January 2007	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation.
23 November 2006	Change of MAH.
20 October 2006	Change of name of manufacturing site for the active substance.
16 December 2005	Renewal.
19 October 2005	Removal of test method performed on the finished product.
16 November 2004	Changes to the SPC and Product Literature to bring in line with new legislation.
22 December 2003	Addition of a manufacturer of the active substance.
09 May 2003	Change of manufacturer of the active substance.
21 June 2001	Renewal.
17 December 1996	Renewal.