Veterinary Medicines Directorate

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# Post Authorisation Assessments

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

Vm 10434/4016

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| • | 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.<br>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’. |

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| • | 22 March 2007 | Change to specification of the finished product. |
| • | 16 January 2007 | Change of legal category from POM to POM-V.<br>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. |