



Post Authorisation Assessments

Enacard Tablets for Dogs 20mg

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| • | 28 May 2020 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| • | 01 November 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. |
| • | 10 December 2014 | Addition of a manufacturer of the active substance, supported by a new Ph. Eur. Certificate of Suitability. Replacement of a test for the active substance. |
| • | 26 November 2009 | Change of storage conditions from 'Do not store above 30°C' to 'Do not store above 25°C'. |
| • | 09 September 2008 | Renewal. |
| • | 28 August 2008 | Change in test procedure performed on the finished product. |
| • | 08 August 2008 | Change in test procedure performed on the finished product. |
| • | 15 July 2008 | Addition of a manufacturing site for all of the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. |
| • | 13 May 2008 | Addition of a new manufacturer responsible for batch control and testing. Deletion of a packaging site for the blister presentation. Deletion of a batch release site for the finished product. |
| • | 18 April 2007 | Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation. |
| • | 04 November 2004 | Addition of a site of batch release. Addition of a manufacturer for assembly of the blister presentation. |
| • | 13 February 2004 | Renewal. |
| • | 22 January 2004 | Minor changes to the specification of the active substance. Minor changes to methods of control for the finished product. |
| • | 10 October 2003 | Minor changes to the manufacturing process of the active substance. |
| • | 21 February 2001 | Change of finished product specification. |
| • | 07 December 2000 | Change of in use shelf life. |
| • | 21 June 2000 | Change of name of product from 'Enalfor Tablets for |

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| | | Dogs 20mg' to 'Enacard Tablets for Dogs 20mg'. |
| • | 30 November 1999 | Addition of an assembly site of the dosage form. |