Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Ubro Yellow Milking Cow Intramammary Suspension

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| • | 09 November 2018 | Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS. |
| • | 13 September 2018 | Change in the name of a manufacturer used in the manufacture of the active substance. |
| • | 13 December 2017 | Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer. |
| • | 25 October 2017 | Minor changes to an approved test procedure of the finished product. |
| • | 03 August 2017 | Submission of an updated Ph. Eur. certificate of suitability for an active substance.<br>Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.<br>Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.<br>Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place. |
| • | 27 April 2017 | Decrease in batch size range of the finished product.<br>Addition of a secondary packaging site of the finished product.<br>Addition of a manufacturer responsible for importation and/or batch release where batch control/testing takes place.<br>Addition of a manufacturing site of the finished product. |
| • | 15 February 2017 | Change to a test procedure. |
| • | 18 January 2017 | Introduction of a re-test period of the active substance.<br>Introduction of a re-test period of the active substance. |
| • | 22 June 2016 | Submission of an updated Ph. Eur. certificate of suitability<br>Submission of an updated Ph. Eur. certificate of suitability |
| • | 22 June 2016 | Addition of a QC site of API (Fareva - Prednisolone).<br>Addition of a QC site of API (Fareva - Prednisolone).<br>Submission of an updated Ph. Eur. certificate of suitability: (Prednisolone - Sanofi)<br>Extension or introduction of a re-test period/storage period supported by real time data<br>Change in the specification parameters of an active substance |

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| • | 25 May 2016 | Change to widen the specification parameters of the active substance.<br>Change to widen the specification limits of the active substance. |
| • | 02 February 2016 | Change in the specification parameters and/or limits of the finished product<br>Change in the specification parameters and/or limits of the finished product<br>Change in the specification parameters and/or limits of the finished product |
| • | 20 August 2015 | Change in the name of the manufacturer of the active substance. |
| • | 24 April 2015 | Submission of updated Ph. Eur. Certificates of Suitability.<br>Change in batch size of the active substances.<br>Introduction of a re-test period. |
| • | 16 July 2014 | Addition of two new sites for active substance manufacture, addition of a site for batch release and testing of the active substance and addition of a new primary packaging for the active substance. |
| • | 14 May 2013 | Change in the name of a manufacturer of the finished product. |
| • | 05 December 2012 | Deletion of a manufacturing site of the active substance. |
| • | 02 May 2012 | Addition of an updated EDQM certificate of suitability from an already approved manufacturer of the active substance. |
| • | 24 April 2012 | Change in the name of the manufacturer of the finished product and batch release site. |
| • | 06 May 2011 | Change of the site for batch control and batch release. |
| • | 06 May 2011 | Change in the site of manufacturer of the active substance (micronisation). |
| • | 06 May 2011 | Change in the site of manufacturer of the active substance (sterilisation). |
| • | 06 May 2011 | Deletion of a manufacturing site responsible for sterilisation, micronisation, batch control, and batch release of the active substance. |
| • | 29 March 2011 | Addition of a manufacturer for the non-sterile active substance. |
| • | 21 December 2009 | Deletion of a manufacturing site of the finished product/ |
| • | 28 August 2008 | Addition of a manufacturer of the active substance. |
| • | 29 July 2008 | Change of name of the product from ‘Leo Yello Milking Cow Intramammary Suspension’ to ‘Ubro Yello Milking Cow Intramammary Suspension’. |
| • | 24 October 2007 | Changes to the SPC and product literature to bring them into line with new legislation. |
| • | 24 October 2007 | Change of legal category from POM to POM-V. |
| • | 28 June 2007 | Addition of an alternative supplier of the primary packaging and change in batch size of finished product. |
| • | 10 May 2007 | Addition of a manufacturing site for the finished product. |
| • | 11 February 2007 | Change in the batch size of the finished product. |
| • | 11 February 2007 | Change to batch release arrangements and quality control testing of the finished product. |
| • | 09 May 2006 | Renewal. |
| • | 28 February 2006 | Change in the MAH. |

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| • | 11 January 2006 | Change in the re-test period of the active substance. |
| • | 05 August 2005 | Addition of a distributor. |
| • | 28 July 2005 | Reduction in shelf life of the finished product. |
| • | 12 May 2005 | Change to labelling relating to the name of the MAH. |
| • | 08 October 2004 | Milk withdrawal period change. |
| • | 17 September 2004 | Addition of a manufacture of the active substance. |
| • | 08 October 2001 | Renewal. |
| • | 05 October 2001 | Change to manufacturer of the active substance. |
| • | 30 July 2001 | Change to manufacturer of the active substance. |
| • | 30 July 2001 | Reduction of shelf life. |
| • | 30 July 2001 | Change to formulation. |
| • | 05 May 1998 | Additional presentation. |
| • | 29 November 1996 | Renewal |
| • | 14 November 1996 | Change to withdrawal periods. |