Veterinary Medicines Directorate

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Post Authorisation Assessments

Ubro Red Dry Cow Intramammary Suspension

•	14 March 2019	Minor change in the manufacturing process of the active substance.
•	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.
•	09 February 2017	Changes to a test procedure (including addition) for the active substance.
•	18 January 2017	Introduction of a re-test period of the active substance.
•	10 November 2015	Deletion of a manufacturing site for an active substance.
•	02 September 2015	Change in name of manufacturer of active ingredients.
•	20 May 2015	Change to the specification limits of the finished product.
•	24 April 2015	Submission of updated Ph. Eur. Certificates of Suitability. Change in batch size of the active substances. 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 manufacturer of the finished product and site of batch release.
•	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 of name of manufacturer of the finished product and site of batch release.
•	29 December 2009	Submission of an EDQM certificate of suitability for an additional manufacturing site of the active substance.
•	21 December 2009	Deletion of a manufacturing site.
•	28 August 2008	Addition of a manufacturer of the active substance.
•	29 July 2008	Change of the name of the product from Leo Red Dry Cow to Ubro Red Dry Cow.
•	12 December 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	12 December 2007	Change of legal category from POM to POM-V.
•	11 October 2007	Addition of a primary pack type and change in batch size.
•	11 October 2007	Addition of site of manufacturer and assembler of dosage form.

•	28 September 2007	Addition of a site of batch release.
•	12 July 2006	Renewal.
•	28 February 2006	Change of name and address of MAH.
•	11 January 2006	Change in re-test period.
•	05 August 2005	Addition of a distributor.
•	28 July 2005	Change in shelf life.
•	12 May 2005	Change to labelling relating to name of MAH.
•	17 September 2004	Additional manufacture of the active substance.
•	22 December 2003	Change of indications.
•	26 June 2003	Change in the name of the manufacturer of the active substance.
•	14 March 2003	Addition of a manufacturer.
•	09 October 2001	Renewal.
•	03 October 2001	Change to manufacturer of active substance.
•	31 January 2001	Change to manufacturer of the active substance.
•	17 September 1996	Renewal.
•	14 August 1995	Additional formulation.