Veterinary Medicines Directorate

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Post Authorisation Assessments

Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for Cattle

Vm 08327/5059

10 December 2024	One-off alignment of the product information with version 3 of the GB QRD templates.
20 July 2024	Extension of active substance retest period.
23 April 2024	Reduction of the shelf-life as packaged for sale from three years to two years. Addition of a new specification parameter to the finished product specification. Addition of a new specification parameter to the finished product specification. Addition of a new specification parameter to the finished product specification. Addition of a new specification parameter to the finished product specification. Addition of a new specification parameter to the finished product specification. Addition of a new specification parameter to the finished product specification. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
06 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
05 January 2023	Change in the name of a manufacturer of active substance. Change in the name of a manufacturer of active substance.
14 July 2022	Change in the name of a manufacturer of active substance. Change in the name of a manufacturer of active substance.
18 March 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
31 July 2019	Change in the name of a manufacturer.
06 March 2019	Change in the QPPV of an existing pharmacovigilance

	system as described in the DDPS.
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.
22 August 2018	Change in the invented name of the veterinary medicinal product in SI only.
05 June 2018	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
01 May 2018	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes of the finished product. Change in the invented name of the veterinary medicinal product from Ubrostar Dry Cow Intramammary Suspension for cattle to Ubrostar Red 100 mg / 280 mg / 100 mg, Intramammary Suspension for cattle.
20 December 2017	Changes to the labelling or package leaflet.
25 October 2017	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
21 August 2017	Increase in batch size of the active substance used in the manufacturing process of the active substance. Increase in batch size of the active substance used in the manufacturing process of the active substance. Changes to a test procedure for the active substance Changes to the quality control testing arrangements for the active substance of a site where batch control / testing takes place. Changes to the quality control testing arrangements for the active substance of a site where batch control / testing takes place. Extension of a re-test period of the active substance. Extension of a re-test period of the active substance.
24 February 2017	Renewal – UK as CMS.
03 June 2016	Change to batch release arrangements and quality control testing of the finished product (addition of Haupt Pharma Latina SRL). Addition of a secondary packaging site of the finished product. Decrease in batch size range of the finished product. Addition of a manufacturing site of the finished product.
08 February 2016	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability Submission of an updated Ph. Eur. certificate of suitability
07 September 2015	Changes to an existing pharmacovigilance system as described in the DDPS.
27 August 2015	Change in the name of two manufactures of the active substance.
29 August 2014	Addition of a manufacturer for the active substance.
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.
18 March 2014	To change the name and address of a manufacturer of the finished product responsible for batch release.
04 January 2013	To change the MAH from Cyton Biosciences Ltd. to Boehringer Ingelheim Ltd.
19 June 2012	Addition of a manufacturer for batch control and release of the active substance framycetin sulphate.
19 June 2012	Addition of a manufacturer for micronisation of the active substance framycetin sulphate.
19 June 2012	Addition of a manufacturer for sterilisation of the active substance framycetin sulphate.
19 June 2012	Addition of a new manufacturer of the active substance supported by a certificate of suitability framycetin sulphate.
07 March 2012	Introduction of a new pharmacovigilance system.