Veterinary Medicines Directorate

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Post Authorisation Assessments

Ubroseal Blue Dry Cow 2.6 g Intramammary Suspension for Cattle

Vm 05150/5000

•	20 July 2024	Change(s) in the SPC, labelling or package leaflet of a generic or hybrid medicinal product following assessment of the same change(s) for the reference product.
•	20 July 2024	One-off alignment of the product information with version 9.0.
•	21 June 2024	Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: -Introduction of a manufacturer of the active substance supported by an ASMF.
•	17 November 2023	Submission of a new Ph. Eur. certificate of suitability for active substance.
•	14 April 2023	Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible.
•	20 July 2022	Unlimited renewal.
•	16 June 2020	Addition of components (excipients) of the flavouring or colouring system of the finished product. Change in the invented name of the veterinary medicinal product from Ubroseal Dry Cow 2.6 g Intramammary Suspension for Cattle to Ubroseal Blue Dry Cow 2.6 g Intramammary Suspension for Cattle.
•	13 January 2020	Deletion of a test procedure for the finished product. Increase in batch size from 200 – 400 kg to 200 – 1230 kg of the finished product. Minor change in the manufacturing process.
•	25 September 2019	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months.
•	02 April 2019	Addition of a site where batch control/testing takes place.
•	06 February 2019	Change of distributor details from Boehringer Ingelheim Limited GB to Boehringer Ingelheim Animal Health UK Ltd.
•	06 December 2018	Update to the Local Representative details.
•	21 February 2018	Change in the RMS from UK to IE