Veterinary Medicines Directorate

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Post Authorisation Assessments

Downlands Calcium Borogluconate 40% w/v CM Solution for Injection

Vm 02000/4214

•	1 June 2023	Deletion of a supplier of the bromobutyl bung.
•	25 May 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	03 January 2023	Change of Distributor address from: Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co Down, Northern Ireland.
•	01 December 2021	Addition of a supplier of packaging components or devices.
•	16 November 2021	Tightening of in-process limits applied during the manufacture of the finished product. Increase in batch size (From – 1000 L To – 1000 L and 4000 L) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	19 August 2021	Submission of a new certificate of suitability for an active substance. Submission of a new certificate of suitability for an active substance.
•	21 July 2021	Minor changes to an approved test procedure of the finished product
•	21 July 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	05 November 2020	Change in distributor details from Downland Marketing Limited, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
•	18 September 2020	Change in test procedure for the finished product.
•	27 July 2018	Changes to the labelling and package leaflet. Update distributor details on the QRD text.
•	13 June 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	13 June 2017	Change in the name of the active substance supplier. Deletion of a supplier of the active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	04 May 2011	Change in test procedure performed on the finished

		product
•	09 July 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	21 March 2007	Change of legal category from PML to POM-VPS
•	11 January 2006	Renewal
•	12 December 2005	Addition of a site of assembly
•	10 January 2003	Change of shelf life from 12 months to 18 months
•	14 June 2002	Change of distributor