Veterinary Medicines Directorate

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Post Authorisation Assessments

Calciject 40 CM Solution for Injection

Vm 02000/4125

17 March 2026	Submission of an updated Ph. Eur. CEP for an active substance.
12 November 2025	Submission of a Ph Eur. CEP for an active substance.
31 July 2024	Change in test procedure for the finished product.
01 June 2023	Deletion of a supplier of bromobutyl bung.
26 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.
28 October 2022	Change in distributor details 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.
03 November 2021	Addition of a supplier of packaging components or devices.
26 October 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.
16 July 2021	Minor changes to an approved test procedure of the finished product.
24 March 2020	Change in test procedure for the finished product
30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
13 June 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
07 April 2014	Deletion of a manufacturer and change of name of a manufacturer.
02 November 2011	Change of distributor
04 May 2011	Change in test procedure performed on the finished product
05 December 2008	Renewal
29 May 2008	Changes to the SPC and Product Literature to bring in line with new legislation

07 February 2007	Change of legal category from POM to POM-VPS
11 August 2005	Addition of a site of assembly
19 July 2004	Renewal
17 October 2002	Change of shelf life from 12 months to 18 months
15 June 2001	Change of type of sterile container
31 January 2001	Renewal
09 September 1998	Change of manufacturing site of the dosage form
22 August 1995	Change of specification of the finished product
19 April 1995	Additional presentation