



## Post Authorisation Assessments

### Calciject 40 Solution for Injection Vm 02000/4069

•	13 April 2024	Change in shape or dimensions of the container or closure (immediate packaging): - Sterile medicinal products. Change in the batch size (including batch size ranges) of the finished product: - Other changes. Change in the manufacturing process of the finished product.
•	13 April 2024	Changes to the quality part of the dossier: Deletion of - one of the authorised containers for the finished product. Editorial changes to part 2 of the dossier.
•	18 July 2023	Change in part of the primary packaging material not in contact with the finished product formulation.
•	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, Co. Down, BT35 6QQ, Northern Ireland.
•	20 August 2021	Submission of a new certificate of suitability for an active substance. Submission of a new certificate of suitability for an active substance.
•	22 April 2020	Tightening of specification limits of 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.
•	22 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
•	15 March 2006	Renewal
•	12 October 2005	Addition of a site of assembly
•	14 March 2002	Renewal
•	09 September 1998	Change of manufacturing site of the dosage form
•	12 March 1998	Change of type of sterile container Renewal