

Post Authorisation Assessments

• 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.
• 07 April 2014	Deletion of a manufacturer and change of name of
	manufacturer.
• 28 November 2013	Change of manufacturer of the active substance.
• 08 August 2012	Change of distributor
• 27 July 2011	Change in test procedure performed on the finished product
• 11 March 2008	Changes to the SPC and Product Literature to bring ir line with new legislation
• 07 February 2007	Change of legal category from POM to POM-VPS
• 22 January 2007	Renewal
• 11 August 2005	Addition of a site of assembly
• 17 October 2002	Increase of product shelf life from 12 to 18 months
• 23 June 2001	Change of type of sterile containers
• 17 August 2000	Renewal
09 September 1998	Change of manufacturing site of dosage form
• 15 May 1996	Addition of a supplier of the active substance

Calciject 20CM Solution for Injection