



Post Authorisation Assessments

Dunlop's 40 CM Solution for Injection

•	23 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.
•	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
•	05 December 2008	Renewal
•	05 November 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 March 2007	Change of legal category from PML to POM-VPS
•	11 November 2005	Addition of a manufacturing site of assembly
•	15 July 2004	Renewal
•	16 January 2004	Change of distributor
•	13 January 2003	Change of shelf life from 12 months to 18 months