



Post Authorisation Assessments

Frusecare 40mg Tablets

•	08 August 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	03 November 2016	Change in the address of the Marketing Authorisation Holder.
•	07 March 2014	Change of distributor.
•	18 September 2013	Change in test procedure performed on the finished product
•	27 August 2013	Change in specification of the finished product
•	19 April 2012	Change to packaging component of the immediate packaging
•	09 February 2010	Change of MAH
•	20 November 2008	Minor changes to the manufacturing process of the active substance
•	04 November 2008	Renewal
•	26 February 2008	Change of tests performed on the finished product Change of shelf life of the finished product from 5 years to 4 years
•	16 August 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature
•	05 October 2005	Renewal
•	24 August 1999	Change of specification of the finished product