



Post Authorisation Assessments

Prilenal 5 mg Tablets

•	19 September 2017	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.
•	06 January 2016	Submission of an updated DDPS.
•	11 October 2013	Variation to update the DMF and change the QPPV contact.
•	13 February 2012	To change the UK Marketing Authorisation Holder address.
•	06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only.
•	28 April 2010	Change in the manufacturing process of the finished product.
•	19 October 2009	Renewal – UK as CMS.