



Post Authorisation Assessments

Hipragumboro G97

Vm 17533/5026

•	21 October 2021	Deletion of a specification parameter of the finished product.
•	15 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 May 2018	Change in RMS from UK to FR.
•	16 March 2018	Repeat use MRP to add 3 new member states
•	04 February 2016	Change in the name of the local UK representative.
•	20 May 2011	Addition of two presentations – one vial of 1000 doses and one vial of 5000 doses
•	17 November 2010	Change of distributor
•	20 January 2010	Changes to comply with Ph. Eur.
•	14 January 2009	Renewal
•	07 September 2007	Change of shelf life of the finished product from 12 months to 24 months
•	25 July 2007	Change of distributor
•	18 January 2005	Repeat Use
•	26 November 2003	Mutual Recognition procedure, UK as RMS