



Post Authorisation Assessments

Apotil 300 mg/ml Solution for Injection Vm 36308/4000

•	03 October 2017	Change in the specification limits of the finished product.
•	04 September 2017	Change in the address of the marketing authorisation holder from Windsor House, Barnett Way, Barnwood, Gloucester, GL4 3RT to Staverton Court, Staverton, Cheltenham, Gloucestershire, GL51 0UX. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS Changes to the DDPS.
•	11 April 2016	Renewal
•	19 November 2014	Addition of an alternative manufacturer of the active substance.
•	03 April 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 34 referral procedure.