Post Authorisation Assessments

Hypnorm Solution for Injection
Vm 41760/4000

•	15 July 2015	Addition of a manufacturing site for the finished product and for secondary packaging.
•	17 March 2015	Submission of a new Ph. Eur. Certificate of Suitability.
•	20 December 2012	Change to specification limits for the finished product Change of batch size Change of shelf life from 18 months to 36 months Addition of a manufacturer of the finished product Addition of a manufacturing site for secondary packaging Addition of 3 manufacturing sites responsible for batch control and testing
•	24 October 2012	Change of MAH
•	02 April 2009	Change of specification of the finished product
•	05 February 2009	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	15 January 2009	Change of name and address of the manufacturer of the active substance
•	12 August 2008	Change of batch size of the finished product
•	20 July 2007	Addition of a pack size of 1x10ml vial
•	27 September 2006	Addition of a test procedure performed on the finished product
•	01 November 2005	Renewal
•	22 December 2004	Change of manufacturer and assembler of the dosage form
•	06 October 2004	Change of distributor Change of MAH
•	06 June 2003	Renewal
•	21 March 2000	Change of shelf life from 24 months to 18 months
•	15 July 1997	Change to specification of the finished product
•	18 September 1995	Change to storage conditions