Post Authorisation Assessments

Hypnorm Solution for Injection

Vm 41760/5000

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