

Post Authorisation Assessments

Hypnorm Solution for Injection

Vm 41760/4000

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| • | 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 |