



Post Authorisation Assessments

Pethidine 50mg/ml Solution for Injection Vm 10434/4031

•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	03 November 2015	Change to the address of the marketing authorisation holder
•	19 November 2014	Change to the text in section 4.11 of the SPC and relevant sections of the product literature.
•	25 February 2013	Variation to change the supplier of a packaging component.
•	03 January 2011	Variation to change the Distributor.
•	14 July 2008	Minor change in the manufacturing process of the Active Substance.
•	14 July 2008	Minor alterations to the SPC and Product Literature.
•	13 February 2008	Renewal.
•	16 August 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	10 May 2007	Variation to change the Marketing Authorisation Holder.
•	11 March 2004	Renewal.
•	06 October 1998	Renewal.