



Post Authorisation Assessments

Milbotyl 300 mg/ml Solution for Injection Vm 08749/4023

• 12 January 2018	Change in the specification limits of the finished product.
• 04 June 2015	Renewal – UK as CMS
• 07 August 2014	To add a new manufacturer of the active substance that is supported by an ASMF.
• 02 July 2014	To delete a manufacturing site of the product.
• 07 April 2014	Changes to the SPC and product literature following an EU Directive.
• 23 March 2011	To amend the number for the poisons unit in the UK.