



Post Authorisation Assessments

Domidine 10 mg/ml Solution for Injection for Horses and Cattle Vm 16849/4008

• 23 March 2022	Tightening of specification limits of an active substance. Tightening of specification limits of an active substance. Tightening of specification limits of an active substance. Change in the specification parameters of an active substance. Minor change to the restricted part of an Active Substance Master File.
• 02 March 2022	Increase in batch size (from 10-50 L to 10-250 L) of the finished product.
• 24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 09 August 2017	Changes to the labelling or package leaflet.
• 14 June 2016	Addition of specification tests to active substance specification. Tightening of limits in active substance specification. Extension of retest period of active substance.
• 31 May 2013	Change in name and contact details for QPPV
• 08 March 2013	To extend the shelf life of the product as packaged for sale from 2 years to 3 years.
• 04 January 2013	To approve mock-ups.
• 04 September 2012	To change the distributor to Dechra Veterinary Products Ltd.
• 16 December 2011	To change the distributor.
• 16 December 2011	Renewal procedure – UK as CMS
• 23 February 2011	To change the distributor.