



Post Authorisation Assessments

Busol – 0.004 mg/ml Solution for Injection for Cattle, Horses and Rabbits Vm 24745/4000

• 18 June 2024	Change of distributor address from Cougar Lane, Naul, Co. Dublin, Ireland to Block 3, Unit 9, CityNorth Business Campus, Stamullen, Co. Meath, K32 D990, Ireland.
• 08 June 2022	Change in storage conditions of the finished product.
• 22 March 2022	Deletion of manufacturing site for an active substance.
• 02 December 2020	Increase in batch size (200 L to a range of 200 L - 500 L) of the finished product.
• 15 March 2017	Extension of retest period for active substance. Addition of a site of manufacture of active substance supported by a certificate of suitability.
• 17 December 2014	Addition of a secondary packaging site for the finished product.
• 28 November 2012	To change the QPPV.
• 07 November 2012	Addition of a site for manufacturing and batch control testing.
• 29 March 2010	Renewal MA
• 29 July 2009	To add an additional batch control/testing site.
• 30 January 2009	Change in shelf life of the product as packaged for sale.
• 11 September 2008	Change of distributor.
• 22 May 2008	Change in shelf life.
• 09 May 2008	Change of name from Generhal – 0.004mg/ml – Solution for Injection for Cattle, Horses and Rabbits to Busol – 0.004mg/ml – Solution for Injection for Cattle, Horses and Rabbits.
• 28 April 2008	Change to batch release arrangements/QC testing.
• 28 April 2008	Replace/add manufacturing site: secondary packaging.
• 23 August 2006	Change of name from Burserelein aniMedica 0.004 mg/ml - solution for injection to Generhal – 0.004mg/ml – Solution for Injection for Cattle, Horses and Rabbits.

