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Post Authorisation Assessments

Oxytocin-S, 10 iu/ml, Solution for Injection Vm 01708/4314

• 18 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 30 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
• 25 February 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 8 November 2019	Changes to the labelling and package leaflet.
• 08 July 2019	Deletion of manufacturing site for a finished product.
• 01 March 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 20 August 2015	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance manufacturer.
• 16 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance manufacturer.
• 04 July 2012	Reduction in shelf life from 5 to 3 years.
• 15 June 2011	Submission of an EDQM certificate of suitability for a new supplier of the active substance.
• 09 April 2010	Minor change to an approved test procedure of the finished product.
• 29 July 2009	Update to the Part II dossier.
 15 January 2009 	Renewal
• 17 August 2007	Change in the name of an active substance manufacturer.
 27 February 2007 	Change in immediate packaging material.
• 24 August 2006	Changes to the SPC and product literature to bring them into line with new legislation.
• 30 June 2005	Renewal
• 20 April 2005	Change of address of a distributor.
• 07 October 2002	Addition of a site of manufacture of the finished product, packaging and batch release.
• 03 July 2001	Addition of a distributor.
• 22 June 2000	Change in address of MAH.
• 01 March 2000	Renewal
• 09 January 1997	Addition of indications and change to recommended dose and dosage schedule.