Veterinary Medicines Directorate

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Post Authorisation Assessments

Lignol 2.0% w/v Solution for Injection

Vm 10434/4028

•	15 June 2022	Updated certificate of suitability for an active substance.
•	27 March 2020	Addition of a site where batch control/testing takes place.
•	10 September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	31 May 2018	Submission of a new Ph. Eur. certificate of Suitability for an active substance from a new manufacturer.
•	04 October 2017	Changes to the labelling and/or package leaflet.
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	12 January 2015	Submission of a new Ph. Eur. Certificate of Suitability for a new active substance manufacturer.
•	25 February 2013	Change in supplier of packaging components.
•	19 December 2012	Variation to change the legal category from NFA-VPS to POM-VPS. Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	05 December 2012	Change in the batch size of the finished product. Change in the manufacturing process of the finished product.
•	12 June 2012	Change in the specification parameters.
•	26 January 2011	Variation to change a Distributor.
•	22 January 2010	Variation to submit an updated Certificate of Suitability.
•	23 April 2008	Variation to submit and updated Certificate of Suitability.
•	25 February 2008	Renewal.
•	15 August 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to NFA-VPS.
•	10 May 2007	Change of Marketing Authorisation Holder.
•	18 March 2004	Renewal.
•	13 November 2001	Update Licence Particulars.
•	13 October 2000	Change in finished product specification.
•	06 June 2000	Deletion of cattle and calves from the target species.
•	07 September 1998	Renewal.