Veterinary Medicines Directorate

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Post Authorisation Assessments

Stresnil 40 mg/ml Solution for Injection for Pigs

Vm 00879/4198

•	24 November 2022	Registration of an approved stability protocol for the finished product.
•	18 June 2021	Submission of a new Ph. Eur. certificate of suitability for an active from a new manufacturer.
•	18 March 2021	Changes to the product literature following a Periodic Safety Update Report.
•	15 December 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	09 December 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	17 December 2019	Deletion of manufacturing site for a manufacturer responsible for batch release.
•	08 October 2019	Replacement of a site where batch control/testing takes place. Replacement of a site where batch control/testing takes place. Replacement of a secondary packaging site of the finished product. Minor change in the manufacturing process of a finished product. Change to in-process tests applied during finished product manufacture. Change to in-process tests applied during finished product manufacture. Replacement of a manufacturing site of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 January 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	28 October 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	10 January 2013	Variation to update the European Pharmacopoeia Certificate of Suitability for the active substance.
•	08 November 2012	Addition of a new specification parameter to the specification with its corresponding test method of an excipient.
•	07 November 2012	Addition of a new specification parameter to the specification with its corresponding test method of the

		finished product.
•	19 September 2012	Variation to change the Marketing Authorisation Holder.
•	14 March 2012	Grouped variation to change the distributor.
•	08 June 2011	Variation to change the site of a manufacturer.
•	08 June 2011	Variation to change the batch size.
•	08 June 2011	Variation to make minor amendments to the method of manufacture for the finished product.
•	06 May 2011	Variation to change the site for batch release and batch control testing.
•	05 May 2011	Variation to delete parts of the in-process tests which are non-significant.
•	15 June 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability.
•	30 April 2009	Submission of an updated European Pharmacopoeia Certificate of Suitability.
•	22 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	27 February 2008	Variation to change the address of the Marketing Authorisation Holder.
•	20 September 2007	Variation to update the finished product specification.
•	03 November 2006	Renewal.
•	31 August 2005	Variation to broaden the IPC limits.
•	29 July 2004	Change of active substance manufacturer.
•	16 October 2003	Harmonisation of the SPC.
•	24 July 2001	Variation concerning the assembler of dosage form.
•	30 November 1999	Change to safety warnings.
•	23 November 1999	Renewal.
•	09 October 1997	Variation to update licence particulars.
•	03 January 1997	Change of the name of the finished product.
•	03 January 1997	Renewal.
•	31 August 1995	Change of Importer.