Veterinary Medicines Directorate

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Post Authorisation Assessments

Pulmotil AC 250 mg/ml Concentrate for Oral Solution for use in Drinking Water or Milk Replacer

Vm 00879/4168

•	08 August 2022	Deletion of manufacturing sites for an active substance, secondary assembly and other packaging operations.
•	24 March 2022	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	25 February 2022	Changes to the labelling and/or package leaflet.
•	01 February 2022	Minor changes to an approved test procedure of the finished product.
•	08 October 2021	Decrease in batch size (from (± 5%) to (± 6.5%)) of active substance used in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	14 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	24 September 2020	Change of MAH 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.
•	03 September 2020	Harmonisation of SPC/QRD following a referral procedure.
•	27 May 2020	Change in batch size range of the active substance. Change in immediate packaging of the liquid active substance.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 January 2019	Changes to the SPC and package labelling.
•	03 October 2018	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product.
•	12 November 2014	Change to the name of the active substance manufacturer.
•	13 May 2013	Variation to change the name of the primary and secondary manufacturer, including quality control sites.
•	02 September 2012	Variation to change the test procedure for an excipient.
•	01 February 2012	Addition of a manufacturer responsible for finished product (including all packaging operations).
•	13 September 2011	Increase of product shelf life.
•	21 June 2011	Addition of an active substance manufacturer.
•	29 November 2010	Addition of a site for labelling and secondary packaging.

•	24 November 2010	Extension of the shelf life of the finished product.
•	03 March 2010	Variation to submit a revised SPC and Product Labelling/Leaflet following formal advice from the VMD.
•	05 January 2010	Variation to change the batch release arrangements and quality control testing of the finished product.
•	22 April 2009	Addition of a non-food target species.
•	11 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.
•	20 November 2008	Extension of product shelf life.
•	12 March 2008	Minor change in the manufacturing process of the active substance.
•	04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
•	30 October 2006	Renewal.
•	04 October 2006	Change in the test procedure for the active substance or starting material, intermediate, or reagent used in the manufacturing process of the active substance.
•	22 September 2003	Line Extension.
•	22 August 2000	Variation to increase the shelf life and retest period of the active substance.