Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetrazin 6% w/v Pour-on Solution

•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	24 November 2011	Variation to seek approved of an additional batch size.
•	26 January 2011	Renewal.
•	22 December 2010	Variation to amend section 4.11 on the SPC.
•	08 July 2009	Variation to change the composition of the finished product.
•	21 January 2009	Variation to change a manufacturing site responsible for part or all of the manufacturing process of the finished product.
•	19 December 2008	Change to the batch release arrangements and quality control testing of the finished product.
•	15 May 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	27 December 2007	Variation to change the address of the Marketing Authorisation Holder
•	28 March 2007	Replacement of a manufacturing site.
•	28 March 2007	Change in the qualitative and or quantitative composition of the immediate packaging material.
•	13 March 2007	Change in the batch release arrangements and quality control testing of the finished product.
•	12 February 2004	Addition of a batch size.
•	03 February 2004	Change to the manufacturing process.
•	25 October 2001	Extension of the finished product shelf-life.
•	25 October 2001	Change of address of the Marketing Authorisation Holder.
•	29 June 2001	Renewal.
•	20 August 1999	Change in the manufacturer of dosage form.
•	19 August 1999	Change of assembler of dosage form.
•	17 March 1999	Change of formulation of the finished product.
•	17 March 1999	Change of manufacturer of the active substance.

•	29 April 1998	Variation concerning the addition of packaging details.
•	29 April 1998	Change of formulations of the finished product.
•	28 November 1997	Addition of a pack size.
•	12 September 1997	Change of Marketing Authorisation Holder.
•	12 September 1997	Change of formulation of the finished product.
•	19 October 1995	Change to the indications and the recommended dosing schedule.
•	19 October 1995	Change to the safety warnings/shelf life.
•	19 April 1995	Change to the manufacturer of dosage form.
•	13 February 1995	Change of active substance manufacturer.