Veterinary Medicines Directorate

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Post Authorisation Assessments

Beaphar One Dose Dog Wormer 500 mg Nitroscanate Film-Coated Tablets

Vm 11990/4010

•	01 December 2023	Change in the specification parameters or limits of the finished product:– tightening of specification limits.
•	03 August 2022	Deletion of a manufacturing site for an active substance. Deletion of manufacturing sites for finished product and assembly. Addition of a manufacturer responsible for batch release.
•	03 August 2022	Substantial changes in the updated version of the ASMF.
•	17 March 2022	Addition of new tests and limits applied during the manufacture of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	17 February 2022	Changes in the SPC & Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	11 November 2021	Addition of a secondary packaging site of the finished product.
•	11 October 2019	Addition of a new container for the finished product.
•	25 July 2019	Widening of the specification limits of a starting material/ intermediate used in the manufacturing process of the active substance.
•	23 May 2018	Change in the invented name of the veterinary medicinal product from Troscan 500 mg Film-Coated Tablets to Beaphar One Dose Dog Wormer 500 mg Nitroscanate Film-Coated Tablets.
•	10 April 2018	Change in distributor details from Beaphar UK Ltd, Homefield Road, Haverhill, Suffolk, CB9 8QP to Beaphar UK Ltd, Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.
•	08 March 2018	Change in the number of tablets in a pack within the range of the currently approved pack sizes of the finished product. Replacement of a manufacturing site responsible for batch release excluding batch control/testing. Addition of a secondary packaging site of the finished product.
•	14 February 2018	Change in distributor details from Chanelle Animal Health Limited, 7 Rodney Street, Liverpool, L1 9HZ, UK to Beaphar UK Ltd, Homefield Road, Haverhill, Suffolk, CB9 8QP, UK.

•	21 September 2015	Change in the specification limits of the finished product.
•	05 August 2015	Change in manufacturer of the active substance. Minor change in manufacturing process of the active substance.
•	04 December 2013	Addition of a pack size.
•	03 November 2011	Deletion of in-process tests used during the finished product manufacturing process.
•	02 November 2011	Introduction of an additional batch size.
•	17 November 2009	Addition of an active substance manufacturer.
•	22 July 2009	Addition of an active substance manufacturer.
•	08 April 2009	Variation to remove a requirement for tablet testing.
•	08 October 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from GSL to AVM-GSL.
•	05 August 2008	Renewal.
•	20 December 2007	Variation to make minor changes to the finished product manufacturing process.
•	28 November 2007	Addition of a batch size of the finished product.
•	15 July 2004	Renewal.
•	08 November 2002	Addition of a manufacturer for part of the manufacturing process.
•	08 November 2002	Change to the specification of the finished product.
•	06 June 2000	Addition of a site of micronisation of the active substance.
•	27 July 1999	Addition of an active substance manufacturer.
•	30 March 1999	Renewal.
•	11 September 1996	Addition of a pack size.
•	11 September 1996	Change of pharmaceutical form.
•	11 September 1996	Addition of a primary assembler of dosage form.
•	07 February 1995	Change of packaging details.