Veterinary Medicines Directorate

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Post Authorisation Assessments

Flubenol 5% w/w Premix for Medicated Feeding Stuff

Vm 00879/5064

14 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
26 March 2024	One-off alignment of the product information with version 3.0*.
18 May 2024	Deletion of titanium dioxide as a component or components of the colouring system.
04 March 2024	Deletion of a site of packaging for the finished product.
30 October 2023	Deletion of a manufacturing site responsible for manufacturing, primary packaging, secondary packaging, labelling, QC & stability testing and QP batch release.
18 January 2023	Submission of an updated certificate of suitability.
01 September 2022	Addition of a batch release site for the finished product. Addition of a batch release site for the finished product. Addition of a manufacturing site of the finished product.
01 September 2022	Change in qualitative or quantitative composition of the immediate packaging. Additional sites for QC testing of the finished product. Additional sites for QC testing of the finished product. Additional site for stability testing of the finished product. Deletion of a non-significant specification parameter for an excipient.
11 June 2021	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
01 October 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.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
10 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 April 2015	Submission of an updated certificate of suitability.
21 March 2012	Change in specification of an active substance Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
07 March 2012	Change of distributor
26 April 2011	Addition of a retest period of 60 months and storage conditions ‘Do not store over 30˚C’for the active substance
21 February 2011	Submission of 2 updated Ph. Eur. Certificates of Suitability for an active substance from an already approved manufacturer
16 February 2010	Addition of a manufacturer of the active substance

30 January 2010	Deletion of an assembler of the dosage form
16 December 2008	Text layout changes to the SPC and Product Literature
27 November 2008	Addition of an immediate container
29 October 2008	Change of legal category from MFX to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
06 March 2008	Replacement of two manufacturing sites of the finished product
27 February 2008	Change of address of the MAH
02 November 2007	Minor change in the manufacture of the finished product
09 October 2007	Change in the batch size of the finished product
30 November 2006	Minor change in the manufacturing process of the finished product
18 September 2006	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
05 July 2006	Change to specification of the finished product Change to in process controls performed on the finished product Change of manufacturing process of the finished product
21 June 2006	Renewal
05 June 2006	Change in batch size of the finished product Change of address of a manufacturer and assembler of the dosage form
22 March 2006	Removal of the 10kg pack size
28 July 2005	Submission of a Ph. Eur. Certificate of Suitability for an active substance
22 December 2003	Renewal
14 June 2001	Change of name of manufacturing site of assembly Addition of a manufacturing site of assembly
20 January 1999	Change to safety warnings
18 November 1997	Addition of manufacturer of the active substance
20 March 1997	Renewal
26 March 1996	Change of withdrawal period for Meat from Pigs from 14 days to 7 days
18 September 1995	Change of importer Change of non-sterile containers Change to dosage particulars
31 May 1995	Change of name and address of the MAH
03 January 1995	Change of specification of the finished product