Veterinary Medicines Directorate

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Post Authorisation Assessments

Flukiver 5% w/v Oral Suspension

Vm 00879/4180

•	05 September 2023	Minor change to a footnote on the shelf-life specification.
•	17 August 2023	Minor editorial changes to part 2 of the dossier. Minor editorial changes to part 2 of the dossier.
•	21 July 2023	Submission of an updated certificate of suitability.
•	02 December 2021	Minor changes to an approved test procedure of the finished product. Minor changes to the approved finished product shelf-life specifications.
•	15 July 2021	Change in the address of a manufacturer of the finished product, also responsible for batch release.
•	18 March 2021	Update of a test procedure to comply with the updated Ph. Eur. monograph.
•	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.
•	26 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	01 November 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 March 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active and submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
•	28 February 2013	Updates to the SPC and Product Literature to bring in line with flukicide legislation
•	30 January 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	24 October 2012	Change of MAH
•	07 March 2012	Change of distributor

•	28 July 2010	Change of specification of excipients to comply with Ph. Eur.
•	07 July 2010	Change of wording of storage condition of the active substance
•	02 June 2010	Updates to the SPC and Product Literature regarding mixing with other products
•	11 November 2009	Introduction of a retest period (36 months) and storage conditions for the active substance
•	27 October 2009	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	17 December 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	05 June 2008	Change of shape of closure nozzle
•	07 March 2008	Change of address of the MAH
•	30 August 2006	Changes in test procedure for a starting material used in the manufacturing process of the active substance Change to specification of a reagent used in the manufacture of the active substance Change to the specification of the active substance Change to the specification of an intermediate produced during the manufacturing process of the active substance
•	15 August 2006	Change in test procedures for a starting material used in the manufacturing process of the active substance
•	12 July 2006	Renewal
•	24 January 2006	Change of manufacturing site of the finished product, quality control testing and batch release Change to specification of the finished product Change of composition of immediate packaging
•	21 November 2003	Changes to the manufacturing process of the active substance
•	12 September 2003	Renewal
•	24 August 2001	Addition of a manufacturing site of secondary assembly of the dosage form
•	16 December 1997	Renewal
•	09 December 1996	Change of specification of the active substance
•	10 January 1996	Change of manufacturing site of the dosage form
•	07 September 1995	Change of importer
•	16 May 1995	Change of withdrawal period for Meat from Sheep from 28 days to 42 days