Veterinary Medicines Directorate

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Post Authorisation Assessments

Fasinex 240, 24% w/v Oral Suspension for Cattle

Vm 00879/4006

•	26 January 2025	Changes in the composition (excipients) of the finished product: - Other changes.
•	29 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	11 August 2022	Addition of a stability testing site for the finished product.
•	12 May 2022	Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	12 May 2022	Addition of an alternative manufacturing batch size of finished product. Change in the in-process test parameter for an in-process test procedure during manufacture of the finished product.
•	03 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 February 2021	Addition of a site where batch control/testing takes place.
•	09 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	18 August 2020	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	16 July 2019	Addition of a site where batch control/testing takes place.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	13 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	19 February 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	05 February 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.

•	06 July 2017	Addition of a new specification parameter with its corresponding test method of the active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	06 April 2016	Change in the manufacturer of the active substance
•	15 December 2015	Change of MAH holder and Distributor from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
•	14 October 2015	Change in specification of the active substance
•	19 December 2013	Extension of shelf life of the product as packaged for sale from 2 years to 3 years.
•	04 July 2013	Renewal.
•	19 December 2012	In light of the recent referral on flukicides without MRLs for milk administered during the dry period of dairy animals, the applicant has provided data to demonstrate that the following withdrawal period statement is acceptable for this product: Not authorised for use in lactating cattle producing milk for human consumption. Not intended for use within 48 days of calving. Milk for human consumption may only be taken from 48 hours after calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken from 50 days after the last treatment.
•	29 September 2010	To de-harmonise the SPC and product literature.
•	24 August 2010	To change the name of the manufacturer of the active substance.
•	09 February 2010	To harmonise the SPC and product literature with IE.
•	26 January 2009	To change the name of the manufacturer of the active substance