Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Fasinex 5% w/v Oral Suspension

•	03 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	1 November 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Deletion of a non-significant specification parameter of the finished product.
•	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

•	22 March 2013	Updates to section 4.7 and 4.11 of the SPC
•	24 August 2010	Change of name of manufacturer of the active substance
•	25 January 2009	Change of name of a manufacturer of the active substance
•	16 June 2008	Batch control
•	01 May 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	21 August 2007	Change of address of MAH and distributor
•	23 May 2007	Renewal
•	03 May 2006	Addition of 12L and 21L pack sizes
•	28 February 2006	Change of legal category from PML to POM-VPS
•	22 February 2006	Change to the manufacturing process of the active substance
•	05 October 2005	Batch control
•	12 May 2005	Addition of a manufacturer of the dosage form
•	20 April 2005	Withdrawal of a manufacturer of the dosage form
•	04 March 2004	Batch control
•	29 July 2003	Submission of an updated Active Substance Master File (ASMF)
•	11 July 2003	Addition of manufacturer of an ingredient used in the manufacture of the active substance
•	05 July 2002	Change of composition of finished product
•	26 April 2002	Change of address of MAH
•	22 February 2001	Renewal
•	22 September 2000	Change of withdrawal period from 28 days to 56 days
•	11 February 1999	Change to manufacturing site of the dosage form
•	11 July 1997	Change of MAH Change of non-sterile containers
•	17 January 1997	Change to safety warnings
•	15 January 1997	Change to manufacturer of the dosage form Renewal
•	14 March 1996	Change to dosage particulars
•	28 September 1995	Addition of a manufacturing site for assembly of the dosage form