Veterinary Medicines Directorate

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Post Authorisation Assessments

Fasinex 10% Oral Suspension for Cattle

•	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.