



Post Authorisation Assessments

Fasinex 100 10% (w/v) Oral Suspension for Cattle and Sheep

•	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.
•	20 December 2012	Renewal.
•	27 August 2010	Extension MA.
•	24 August 2010	To change the name of the active substance manufacturer.
•	25 January 2009	To change the name of the active substance manufacturer.
•	23 October 2008	Decrease of withdrawal period from 56 to 35 days.