Veterinary Medicines Directorate

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Post Authorisation Assessments

Flunixin 50 mg/ml Solution for Injection for Cattle, Horses and Pigs

Vm 02000/4170

•	02 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	02 June 2023	Update to Section 4.5, 5.2 and corresponding sections in PL.
•	16 January 2023	Deletion of a manufacturing site for an active substance.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	23 August 2022	Deletion of a manufacturing site for an active substance.
•	27 January 2022	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	08 July 2021	To update the SPC and labelling intended to implement the outcome of a procedure concerning PSUR. Changes in the composition (excipients) of the finished product.
•	15 April 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	23 January 2019	Change in RMS from UK to DE.
•	23 July 2018	Changes to a test procedure for the finished product.
•	23 January 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.

		Change in the specification parameters and/or limits of the finished product. Change in the specification limits of the finished product.
•	15 January 2018	Increase in batch size (2000 litre and 4000 litre) of the finished product.
•	28 November 2014	Update to the DDPS.
•	23 December 2013	Renewal.
•	26 October 2012	Variation to change the name of the Veterinary Medicinal Product.
•	27 September 2012	Submission of an updated European Pharmacopoeia Certificate of Suitability from an active substance manufacturer.
•	25 January 2012	Variation to change the distributor address.
•	09 August 2010	Repeat Use – To add Iceland as a CMS.
•	16 July 2009	To change the medicinal product name in the UK from “Norixin 50mg/ml Solution for Injection for Cattle, Horses and Pigs” to “Flunixin 50mg/ml Solution for Injection for Cattle, Horses and Pigs”
•	26 March 2009	To change the product name in Sweden from Norixin vet for Cattle, Horses and Pigs to Fluxin N-Vet for Cattle, Horses and Pigs.
•	20 February 2009	MRP (UK as RMS).
•	07 March 2008	Submission of a new European Pharmacopoeia Certificate of Suitability.
•	20 July 2007	Line extension.
•	19 March 2007	Change of legal category from POM to POM-V.
•	06 March 2006	Addition of safety warnings.
•	23 November 2005	Addition of a site of secondary assembly.
•	18 March 2004	Renewal.
•	16 February 2004	Addition of a safety warning.
•	21 August 2003	Addition of a pack size.
•	17 May 2001	Addition of an active substance manufacturer.
•	26 November 1998	Copycat.