Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 02000/4253

•	June 2023	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products.
•	20 January 2023	Deletion of a manufacturer of the 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.
•	25 August 2022	Deletion of a manufacturing site for an active substance.
•	22 February 2022	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	28 April 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 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.
•	25 July 2019	Replacement of an excipient with a comparable excipient.
•	30 May 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	19 October 2018	Change in RMS from UK to FR.
•	26 October 2018	Change in test procedure for the finished product.
•	07 August 2018	Change in the invented name of the veterinary medicinal product in France from Flunixine 5%

		Norbrook to Flunixin Solution Injectable 50 mg/ml Bayer.
•	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.
•	23 January 2018	Increase in batch size (including batch size range*) of the finished product
•	28 November 2014	Update to the DDPS.
•	19 September 2014	Change in distributor details.
•	25 July 2014	Renewal procedure.
•	31 August 2012	Variation to update the certificate of suitability from an already approved manufacturer.
•	03 December 2009	New MA (DCP).
•	19 March 2007	Lateral transfer of legal category.