



Post Authorisation Assessments

Flunixin 50 mg/ml Solution for Injection for Cattle, Horses and Pigs Vm 02000/4170

24 February 2026	One-off alignment of the product information with version 9.0* of the QRD templates. Harmonisation of the generic product after SPC harmonisation of the reference product.
05 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI).
19 January 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
10 December 2024	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB + NI)
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.