



Post Authorisation Assessments

Nuflor Swine 300 mg/ml Solution for Injection

•	28 April 2020	Minor changes to an approved test procedure of the finished product.
•	29 June 2016	Change in the manufacturer of a starting material used in the manufacturing process.
•	06 March 2015	Change in the batch size of the active substance. Tightening of specification limits of the active substance.
•	20 November 2014	Change in test procedure for the active substance. Change in the re-test period of the active substance. To introduce a second manufacturing process.
•	31 July 2014	Deletion of a manufacturing site for the active substance.
•	18 January 2013	Change of MAH. Change in distributor.
•	23 January 2012	Deletion of an active substance manufacturer.
•	02 September 2011	Change in specification limits of the active substance. Change in test procedure for the active substance.
•	14 March 2011	Change of the name of the MAH in Portugal.
•	21 December 2010	Renewal.
•	22 May 2009	Addition of a manufacturer of the active substance.
•	05 June 2008	Amendments to the SPC.
•	28 February 2006	Change container/closure shape/dimensions.
•	24 June 2005	Renewal.
•	19 September 2003	Harmonisation of SPC between original member states and additional member states.