Veterinary Medicines Directorate

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Post Authorisation Assessments

Norixin 5% Solution for Injection

Vm 02000/4137

•	21 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.
•	18 November 2019	Replacement of an excipient with a comparable excipient.
•	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. Addition of a new specification parameter to the specification with its corresponding test method of the finished product Change in the specification parameters and/or limits of the finished product. Change in the specification limits of the finished product.
•	17 January 2018	Increase in batch size (including batch size range*) of the finished product
•	28 November 2014	Update to the DDPS.
•	01 August 2014	Addition of a manufacturing site for secondary assembly.
•	30 August 2012	Submission of an updated Certificate of Suitability for an already approved active substance manufacturer.
•	16 July 2009	Variation to change the name of the veterinary medicinal product.
•	07 February 2007	Change of legal category from POM to POM-V.
•	23 September 2004	Renewal.
•	19 July 2004	Repeat Use.
•	12 March 2004	Variation to bring the SPC in line with the Repeat Use procedure.
•	31 January 2003	Change in the active substance manufacturer.
•	31 January 2003	Change in the pack size.
•	01 March 199	Change of active substance manufacturer.