Veterinary Medicines Directorate

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Post Authorisation Assessments

Nisinject Suspension for Injection

Vm 02000/4227

•	15 January 2020	Replacement of a supplier of packaging components or devices.
•	19 November 2019	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	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.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	08 February 2019	Minor changes to an approved test procedure of the finished product.
•	30 January 2019	Change in RMS from UK to ES.
•	16 January 2019	Introduction of a new site of manufacture.
•	04 September 2018	Replacement of a secondary packaging site of the finished product.
•	01 August 2018	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 April 2016	Deletion of a manufacturing site of the active substance. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	28 November 2014	Update to the DDPS.
•	03 January 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
•	01 February 2013	Change of product name from ‘Nisamox Suspension for Injection’ to ‘Nisinject Suspension for Injection’
•	23 January 2013	Change of distributor
•	14 September 2012	Change of product name in Italy only
•	17 August 2011	Addition of a target species – Dogs
•	06 April 2011	Change of distributor
•	21 August 2009	Renewal
•	11 March 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	20 December 2007	Addition of a manufacturer of an active substance Addition of a manufacturer of an active substance

•	19 March 2007	Change of legal category from POM to POM-V
•	16 July 2004	Mutual Recognition Procedure, UK as RMS
•	14 August 2003	Change of packaging design