Veterinary Medicines Directorate

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Post Authorisation Assessments

Norodine 24 Solution for Injection

Vm 02000/4061

•	01 November 2023	Addition of a supplier of the 100 ml glass vials.
•	30 August 2023	Change in the specification limits of the finished product. Addition of a new in-process control.
•	24 August 2023	Replacement of a test procedure for the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Addition of a specification parameter for the finished product. Addition of a specification parameter for the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
•	05 July 2023	Changes in the SPC, labelling and package leaflet intended to implement the outcome of a referral procedure.
•	03 April 2023	Deletion of a Ph. Eur. certificate of suitability. Submission of a new Ph. Eur. certificate of suitability.
•	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.
•	30 December 2021	Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	19 November 2019	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Increase in batch size of the finished 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.

•	14 November 2016	Submission of an updated certificate of suitability.
•	01 August 2016	Submission of a new certificate of suitability.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 July 2013	Variation to submit updated Ph. Eur. Certificates of Suitability from already approved Active Substance Manufacturers.
•	07 October 2008	Deletion of a manufacturing site.
•	27 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	08 May 2008	Variation to update a Certificate of Suitability.
•	16 January 2008	Addition of an Active Substance Manufacturer.
•	16 January 2008	Addition of an Active Substance Manufacturer.
•	07 November 2007	Renewal.
•	20 February 2007	Transfer of legal category from POM to POM-V.
•	02 November 2005	Addition of an Assembler.
•	11 November 2004	Change of a withdrawal period.
•	12 December 2003	Renewal.
•	29 May 2002	Renewal.
•	11 July 2001	Change to a withdrawal period.
•	27 September 2000	Addition of an Active Substance Manufacturer.
•	09 December 1999	Addition of an Active Substance Manufacturer.
•	08 September 1998	Addition of a Manufacturer and Assembler.
•	12 September 1997	Change to safety warnings.
•	04 June 1997	Addition of an Active Substance Manufacturer.
•	10 October 1996	Change of an Active Substance Manfacturer.
•	18 December 1995	Renewal.