Veterinary Medicines Directorate

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Post Authorisation Assessments

Norocillin 30% w/v Suspension for Injection

Vm 02000/4099

•	28 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	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.
•	24 August 2022	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - As packaged for sale. Change in the shelf-life or storage conditions of the finished product: - Change in storage conditions of the finished product or the diluted/reconstituted product.
•	17 August 2022	Submission of an updated version of an ASMF.
•	04 May 2022	Deletion of a non-significant specification parameter of an excipient.
•	02 March 2022	Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	14 January 2020	Changes to SPC & product literature following a periodic safety update report. (PSUR).
•	21 April 2020	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	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.
•	16 April 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 October 2018	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 1 year for glass vials.
•	16 July 2018	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	23 May 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.

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•	09 February 2017	Addition of a manufacturer of the active substance.
•	30 October 2014	Addition of an active substance manufacturer.
•	23 April 2014	Change of distributor.
•	20 December 2013	Change to the immediate packaging of the finished product and change to the pack size of the finished product.
•	03 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	02 November 2007	Renewal.
•	28 February 2007	Transfer of the legal category from POM to POM-V.
•	10 November 2005	Addition of a site of assembly.
•	25 July 2005	Change of the name of the Active Substance Manufacturer.
•	04 June 2004	Extension of a withdrawal period.
•	06 November 2003	Renewal.
•	28 May 2003	Extension of a withdrawal period.
•	28 May 2003	Extension of a withdrawal period.
•	28 May 2003	Extension of a withdrawal period.
•	21 March 2002	Addition of an Active Substance Manufacturer.
•	12 June 2000	Increase in batch size.
•	09 June 1999	Variation concerning shelf life.