Veterinary Medicines Directorate

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Post Authorisation Assessments

Norocillin 30% w/v Suspension for Injection

Vm 02000/4099

25 March 2025	Submission of updated mock ups.
18 June 2024	To update the SPC and product literature as a result of EMA/V/A/145 – Referral for Procaine Benzylpenicillin.
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. Minor changes to an approved test procedure of the finished product.
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.