Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroclav Injection for Cattle and Dogs

Vm 02000/5021

09 January 2025	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance.
23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
04 July 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (GB)
16 December 2022	Editorial changes to part 2b of the dossier.
22 November 2022	Submission of a new Ph.Eur certificate of suitability for an active substance.
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.
04 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
05 May 2021	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. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
25 August 2020	Changes to a test procedure for the finished product. Changes to a test procedure for the finished product.
18 September 2019	Replacement of a supplier of packaging components or devices.
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.
26 July 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 IE.
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.
24 February 2016	Deletion of a manufacturing site for the active substance. Submission of an updated certificate of suitability. Submission of a new certificate of suitability.
28 November 2014	Update to the DDPS.
03 January 2014	Submission of a Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
02 November 2011	Variation concerning a change in Distributor address.
28 January 2010	Variation concerning the submission of an updated Certificate of Suitability.
16 July 2009	Variation concerning the submission of an updated Certificate of Suitability.
25 June 2009	Renewal.
18 June 2009	Deletion of a site of Active Substance manufacture.
20 December 2007	Addition of an Active Substance Manufacturer.
20 December 2007	Addition of an Active Substance Manufacturer.
07 February 2007	Transfer of legal category from POM to POM-V.
25 January 2005	Addition of a target species.
26 June 2003	Variation concerning the submission of Certificate of Suitability Revisions.
04 February 2003	New EUDE.
20 September 2002	Extension of milk withdrawal period.
20 November 2001	New Marketing Authorisation.