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Post Authorisation Assessments

Carprieve 100 mg Tablets for Dogs Vm 02000/4283

•	13 April 2024	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier. (NI)
•	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)
•	19 January 2024	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier. (GB)
•	30 January 2023	Tightening of specification limits of an excipient.
•	28 October 2022	Change in distributor details from NorbrookLaboratories (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.
•	12 July 2022	Tightening of specification limits of an excipient.
•	09 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 March 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	20 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	17 September 2019	Replacement of a supplier of packaging components or devices. Decrease in batch size range of the finished product. Minor change in the manufacturing process of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.

•	16 September 2019	Addition of a manufacturer responsible for batch release 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.
•	21 May 2019	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	28 November 2014	Update to the DDPS.
•	17 June 2014	Renewal.
•	29 May 2012	Change of distributor - UK.
•	17 June 2011	To change the name of the veterinary medicinal product in Ireland from Norocarp 100 mg Tablets for Dogs to Carprieve 100 mg Tablets for Dogs.