



Post Authorisation Assessments

Carprieve 50 mg/ml Solution for Injection for Cattle Vm 02000/5019

•	06 July 2024	Addition of a new specification parameter for the finished product. Minor change to an approved test procedure for the active substance. (NI)
•	22 May 2024	Minor change to the approved test procedure for the finished product.
•	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)
•	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.
•	16 November 2023	Introduction of a summary of the PSMF. (NI)
•	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.
•	March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 March 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	13 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	30 July 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.
•	22 May 2019	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	24 October 2018	Change in the invented name of the veterinary medicinal product from Carprieve to Carprogesic in FR.
•	22 August 2018	Tightening of specification limits of the finished product. Tightening of specification limits of the finished

		product. Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	17 July 2018	Decrease in batch size range of the finished product.
•	20 July 2017	Changes in the composition (excipients) of the finished product
•	10 September 2015	Updating of a test procedure for the finished product.
•	13 November 2013	Change in the invented name of the veterinary medicinal product in Italy only.
•	22 November 2012	Change in the invented name of the medicinal product from Norocarp 50 mg/ml Solution for Injection for Cattle to Carprieve 50 mg/ml Solution for Injection for Cattle in France only.
•	19 October 2012	Change in invented name of veterinary medicinal product in Germany.
•	11 April 2012	Change of distributor.
•	30 November 2011	Renewal Marketing Authorisation.