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Post Authorisation Assessments

Carprieve 50 mg/ml Solution for Injection for Cattle Vm 02000/4295

_	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.
	20 July 2017 10 September 2015 13 November 2013 22 November 2012 19 October 2012 11 April 2012