



Post Authorisation Assessments

Carprieve 50 mg/ml Solution for Injection for Cattle Vm 02000/3011

01 May 2025	Submission of updated mock ups.
19 January 2025	Change in shape or dimensions of the container or closure. Change in the batch size of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Changes in the composition excipients of the finished product.
20 November 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
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.