



Post Authorisation Assessments

Carprieve 5% w/v Small Animal Solution for Injection

•	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.
•	17 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 December 2020	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	01 June 2020	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	22 November 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
•	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 February 2019	Changes of text to the SPC and package leaflet.
•	25 September 2018	Change in the specification parameter of the finished product.
•	28 June 2018	Minor change in the manufacturing process of the finished product.
•	November 2014	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	January 2012	Change in distributor details. From The Green, Great Corby, Carlisle, Cumbria, CA4 8LR to: 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX.
•	10 February 2011	Renewal
•	12 March 2009	Change of product name from 'Norocarp 5% w/v Small Animal Injection' to 'Carprieve 5% w/v Small Animal Solution for Injection'
•	13 February 2009	Changes to the Product Literature to bring in line with new legislation
•	08 May 2007	Change in specification of the finished product
•	09 August 2006	Change of legal category from POM to POM-V

		Changes to the SPC to bring in line with new legislation
•	23 November 2005	Addition of a site of assembly