Veterinary Medicines Directorate

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Post Authorisation Assessments

Carprieve Tablets 50mg

Vm 02000/4221

•	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.
•	06 June 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	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.
•	22 November 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
•	15 August 2019	Replacement or addition of a supplier of packaging components or devices. Minor changes to an approved test procedure of the finished product. Increase in batch size (including batch size range) of the finished product. 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.
•	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.
•	02 February 2011	Change in specification of the finished product
•	28 January 2009	Change of product name from ‘Norocarp Tablets 50mg’ to ‘Carprieve Tablets 50mg’
•	08 August 2008	Renewal

•	05 October 2006	Change in specification of the finished product
•	21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	11 July 2006	Addition of an indication regarding post-operative pain
•	01 June 2006	Change of shelf life from 18 months (Tubs) and 12 months (Blister) to 26 months (Tubs) and 24 months (Blister)
•	12 December 2003	Addition of presentation (Blister)