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Post Authorisation Assessments

Carprieve 5% w/v Small Animal Solution for Injection

Vm 02000/4229

| | | VIII 02000/4229 |
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| • | 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. |
| • | 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 |
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| | | new legislation |
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| • | 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 |