Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Buprelieve Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses

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| • | 12 October 2022 | Change in address of sterility testing site for the finished product.<br>Update to the identification method listed in the stopper specification for the finished product. |
| • | 03 October 2022 | Change in the specification limits of the finished product. |
| • | 12 August 2022 | Increase in batch size range of finished product. |
| • | 15 February 2022 | Minor changes to an approved test procedure of the finished product.<br>Minor adjustments of the quantitative composition of the finished product with respect to excipients.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 25 June 2021 | National renewal. |
| • | 04 February 2021 | Change in the specification limits of the finished product.<br>Qualitative changes to the excipients. |
| • | 08 June 2020 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 13 March 2020 | Change in the batch size (including batch size ranges) of the finished product. |
| • | 04 February 2020 | Change in the SPC further to a veterinary PSUR. |
| • | 01 May 2019 | Change in the name of the manufacturer of the finished product. |
| • | 30 August 2018 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 31 October 2017 | Increase in batch size (including batch size range) of the finished product. |
| • | 09 August 2017 | Change to part of the (primary) packaging material not in contact with the finished product formulation.<br>Change in the QPPV of an existing pharmacovigilance system as described in the DDPS<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |