Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 42058/5218

18 May 2024	Extension of the shelf life of the finished product as packaged for sale from 30 months to 3 years supported by real time stability data.
13 April 2024	Submission of an updated CEP for the manufacture of an active substance.
24 August 2023	Deletion of the manufacturer responsible for batch release.
21 August 2023	Introduction of the Zoetis DDPS.
14 August 2023	Change of Legal Entity from Jurox (UK) Limited, Second Floor, Richmond House, 105 High Street, Crawley, West Sussex, RH10 1DD to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
10 May 2023	Administrative changes: - Change in distributor details Change to importer, batch release arrangements and quality control testing of the finished product:
12 October 2022	Change in address of sterility testing site for the finished product. 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. Minor adjustments of the quantitative composition of the finished product with respect to excipients. 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. Qualitative changes to the excipients.
08 June 2020	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.
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. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.