



## Post Authorisation Assessments

### Methadyne 10 mg/ml Solution for Injection for Dogs and Cats

Vm 42058/4220

|   |                   |  |
|---|-------------------|--|
| • | 21 September 2023 | Unlimited renewal  |
| • | 24 August 2023    | Deletion of a 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<br>Change to importer, batch release arrangements and quality control testing of the finished product:   |
| • | 20 October 2022   | Change in address of a sterility testing site.<br>Minor changes to an approved test procedure for the immediate packaging.<br>Updated certificate of suitability for an already approved manufacturer.                               |
| • | 25 August 2021    | Change in the fill weight / fill volume of the finished product.<br>Change in the specification limits of the finished product.  |
| • | 11 June 2020      | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.<br>Change in the specification limits of the finished product.   |
| • | 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.                                |
| • | 05 February 2020  | Change in the SPC further to a veterinary PSUR.  |
| • | 22 January 2020   | Increase in batch size from a range of 5 to 50L to a range of 25 to 200L of the finished product.  |