



Post Authorisation Assessments

Methadyne 10 mg/ml Solution for Injection for Dogs and Cats Vm 42058/4220

30 January 2025	Change in the shelf-life of the finished product. Change in the batch size ranges of the finished product.
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 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. Minor changes to an approved test procedure for the immediate packaging. Updated certificate of suitability for an already approved manufacturer.
25 August 2021	Change in the fill weight / fill volume of the finished product. 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. 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. 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.