



Post Authorisation Assessments

AceSedate 10 mg/ml Solution for Injection for Horses Vm 42058/4222

• 24 August 2023	Deletion of a manufacturer responsible for batch release.
• 18 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.
• 26 May 2023	Addition of Distributor: Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP, United Kingdom. Change to importer, batch release arrangements of the finished product- Replacement or addition of a manufacturer responsible for importation and/or batch release.
• 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.
• 27 January 2021	Change in the batch size 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.