



Post Authorisation Assessments

AceSedate 10 mg/ml Solution for Injection for Horses Vm 25296/4008

• 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.