



## Post Authorisation Assessments

### **Pronestestic 40 mg/ml / 0.036 mg/ml Solution for Injection for Horses, Cattle, Pigs and Sheep** Vm 11557/4002

12 February 2025	One-off alignment of the product information with version 9.0* of the QRD template.
10 November 2023	To change the named distributor in GB and NI from Duggan Veterinary Supplies Ltd., Holycross, Thurles, Co. Tipperary, E41A093, Ireland to DUGV (UK) Ltd., Union House, 111 New Union Street, Coventry, CV1 2NT, UK.
27 May 2021	Renewal- UK as CMS.
02 November 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture.
05 May 2020	Reduction of the shelf life of the finished product as packaged for sale from 3 years to 2 years. Change in storage conditions of the finished product from "Store in a refrigerator (2°C-8°C). Keep the vial in the outer carton in order to protect from light" to "Do not store above 25°C. Keep the vial in the outer carton in order to protect from light."
12 February 2020	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product.
03 July 2018	Approval of joint-labelled mock-ups with Ireland.
09 January 2018	Change in distributor details from Support Pharma S.L., General Alvarez de Castro, 39, 28010, Madrid to Duggan Veterinary Supplies Ltd., Holycross, Thurles, Co. Tipperary, E41A093, Ireland.
10 July 2017	Introduction of a new pharmacovigilance system
23 June 2016	Change of MAH from Support Pharma, S.L. to FATRO S.p.A.