



Post Authorisation Assessments

Flordofen 300 mg/ml Solution for Injection for Cattle and Pigs Vm 28365/5008

•	20 October 2024	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone as an excipient. One off alignment with version 9.0 of the QRD template.
•	20 July 2022	Update to an already approved ASMF.
•	06 June 2019	Repeat Use application to add 5 new member states
•	13 November 2018	Changes to the labelling and package leaflet. Change in distributor from Cross Vetpharm Group UK Ltd., Unit 2, Bryan Cefni, Llangefni, Anglesey LL77 7XA, United Kingdom to Duggan Veterinary Supplies Ltd., Holycross, Thurles, Co. Tipperary E41 A093, Ireland
•	18 October 2018	Renewal – UK as CMS
•	09 November 2017	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Change in the manufacturer of a starting material used in the manufacturing process of the active. Minor change to the restricted part of an Active Substance Master File.
•	09 August 2017	Increase in the shelf-life of the finished product as packaged for sale, from 12 to 30 months.
•	07 September 2016	Change in distributor from Vetpharma Animal Health, Spain to Cross Vetpharm Group UK Ltd, United Kingdom.
•	27 July 2016	Change in the batch size of the finished product. Change to batch release site of the finished product Replacement of a specification parameter (of the finished product - Viscosity) as a result of a quality issue. Replacement of a manufacturing site for all of the manufacturing process of the finished product Addition of 50, 100, 250 ml glass vials.
•	29 May 2015	Introduction of a new pharmacovigilance system.
•	14 May 2014	Transfer of MA from Vetpharma Animal Health, S.L. to Dopharma Research B.V.

