



Post Authorisation Assessments

Syncaïne 1000 mg/g Powder for Solution for Fish Treatment Vm 41203/4000

19 December 2024	Replacement of a manufacturer of a finished product responsible for importation and batch release. Change in the address of the Marketing Authorisation Holder from Elara Pharmaservices Limited, Iron Farm, 7 Grimes Gate, Diseworth, Derby, DE74 2QD, United Kingdom to Elara Pharmaservices Limited, 5 Garden Court, Lockington Hall, Main Street, Lockington, Derby, DE74 2RH, United Kingdom.
06 June 2024	Downscaling of batch size for the active substance. Downscaling of batch size for the finished product.
10 May 2024	Tightening of specification limits of an active substance. Tightening of specification limits of a starting material. Tightening of specification limits of the finished product.
12 March 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
04 October 2023	Minor changes to the manufacturing process of the active substance.
25 August 2023	Change of Distributor, from Elara Pharmaservices Limited, Iron Farm, 7 Grimesgate, Diseworth, Derby, DE74 2QD to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ United Kingdom.
13 June 2023	Replacement of a quality control testing site.
16 March 2023	Change in the specification limits of an active substance.
18 January 2023	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance.
20 December 2022	Change in the manufacturing process of the active substance - Other changes.
10 November 2022	Change in legal entity from Callisto Regulatory Consulting Ltd, Iron Farm, 7 Grimes Gate, Diseworth, Derby, DE74 2QD, United Kingdom to Elara Pharmaservices Limited, Iron Farm, 7 Grimes Gate, Diseworth, Derby, DE74 2QD, United Kingdom.
18 October 2022	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.