



Post Authorisation Assessments

Syncaïne 1000 mg/g Powder for Solution for Fish Treatment

Vm 41203/4000

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| • | 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 Pharmservices 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 Pharmservices 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. |