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Post Authorisation Assessments

Repose 500 mg/ml Solution for Injection Vm 41821/4042

10 November 2023 Submission of an updated certificate of suitability. (NI) Submission of an updated certificate of suitability. (NI) 13 December 2022 Updated certificate of suitability from an already approved manufacturer. Updated certificate of suitability from an already approved manufacturer. 07 June 2022 Renewal. 27 January 2021 Changes to SPC and product literature following a periodic safety update report (PSUR). Changes to SPC and product literature following a periodic safety update report (PSUR). 15 August 2019 Introduction of a new pharmacovigilance system.