



Post Authorisation Assessments

Hypertonic 72 mg/ml Solution for Infusion Vm 10434/4091

•	30 December 2022	Replacement certificate of suitability from a new manufacturer.
•	23 March 2022	Renewal
•	18 March 2019	Change in RMS from UK to BE.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	24 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.