



Post Authorisation Assessments

Ketabel 100 mg/ml Solution for Injection Vm 41816/4003

•	09 November 2023	Submission of an updated CEP for ketamine hydrochloride.
•	10 August 2023	Submission of a new Ph. Eur. certificate of suitability.
•	13 July 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, for a starting material/reagent/intermediate used in the manufacturing process of the active substance, or for an excipient: - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Other changes. (GB)
•	26 April 2023	Submission of a new Ph. Eur. CEP from a new manufacture. (NI Change)
•	20 October 2021	Repeat use to add six member states
•	07 October 2021	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR.