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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

UpCard 7.5 mg Tablet

Vm 06462/5015

•	27 October 2023	CEP of active substance manufacturer IPCA laboratories limited is updated.
•	26 July 2023	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter. Minor changes: – to an approved test procedure for active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: intermediate used in the manufacturing process of the active.
•	14 May 2021	Submission of a new Ph. Eur. certificate of suitability for an excipient from a new manufacturer