



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### Fortekor Plus 5mg/10mg Tablets

Vm 52127/5015

•	23 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes to an approved test procedure for the finished product.
•	13 October 2023	Change in the shelf-life or storage conditions of the finished product- Change in the shelf-life or storage conditions of the finished product. Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	18 October 2022	Approval of mock ups.
•	12 July 2022	Updates to an ASMF. Change in the specification parameters and/or limits of an active substance.
•	05 July 2022	Typographical amendment to analytical methods.
•	10 February 2022	Deletion of manufacturing site for an active substance.
•	15 June 2021	Replacement to a test procedure for the finished product.
•	28 May 2021	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control takes place. Changes to the quality control testing arrangements for the active substance – addition of a site where batch control takes place. Changes to a test procedure (including addition) for the active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance.