



Post Authorisation Assessments

Tsefalen 500 mg Film-coated Tablets for Dogs

•	18 September 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 April 2019	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	09 May 2018	Renewal – UK as CMS
•	18 May 2016	Change in address of manufacturer of the finished product.
•	22 September 2015	Replacement of components of the flavouring or colouring system of the finished product
•	30 April 2015	Changes to the labelling that are not connected to the SPC.
•	22 January 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	26 August 2013	Addition of 36 tablet pack size in SE, DK, FI, NO and EE