



Post Authorisation Assessments

Tsefalen 1000 mg Film-coated Tablets for Dogs Vm 58047/4001

•	26 May 2023	Change of MAH from I.C.F. Srl Industria Chimica Fine, Via G.B. Benzoni, 50, 26020 Palazzo Pignano – Cremona, Italy to NEXTMUNE Italy S.R.L., Via G.B. Benzoni, 50, 26020 Palazzo Pignano – Cremona, Italy.
•	01 June 2022	Changes to a test procedure for the finished product.
•	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.
•	10 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 32 Tablet pack size in SE, DK, FI, NO and EE