Veterinary Medicines Directorate

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Post Authorisation Assessments

Tsefalen 1000 mg Film-coated Tablets for Dogs

Vm 58047/4001

18 August 2026	Change(s) in the name of a qualified person for pharmacovigilance (QPPV). (GB) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (GB)
28 April 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI.) Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) (NI.)
10 March 2025	Alignment of the product information with version 9.0* of the QRD templates.
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