

Post Authorisation Assessments

Equipalazone 1g Oral Paste Vm 50406/5035

31 October 2025	Uniformity of dosage units is introduced to replace the currently registered method.
25 April 2025	Change of Marketing Authorisation Holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
25 March 2025	Change to quality testing arrangements for the finished product.
11 March 2025	Alignment of the product information with version 9.0* of the QRD templates.
12 September 2023	Change in test method for the finished product to comply with Ph. Eur. Editorial changes to part 2 of the dossier.
20 February 2023	Deletion of a test procedure for an excipient.
11 January 2023	Change(s) in the composition (excipients) of a non-sterile finished product - replacement of a component or components of the flavouring system.
12 July 2022	Editorial changes to parts 2A and 2B of the dossier.
01 April 2022	Addition of a site where batch control/testing takes place.
15 August 2019	Tightening of in-process limits applied during the manufacture of the finished product.
18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
09 May 2018	Deletion of a manufacturing site for an active substance.
13 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
22 June 2016	Submission of an updated Ph. Eur. certificate of suitability
14 April 2015	Changes to the product labelling/package leaflet.
17 October 2014	Change to the address of the MAH.
07 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
23 May 2012	Addition of an active substance manufacturer
02 March 2011	Changes to the Product Literature artwork
15 December 2010	Change of distributor
05 May 2010	Minor change to manufacturing process of the finished product
20 January 2010	Change of description of product from 'pale yellow' to 'off white'
28 August 2008	Update to withdrawal period on the SPC and Product Literature
11 June 2007	Harmonisation of the SPC

02 January 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
25 October 2006	Change of vanilla flavouring
28 September 2006	Batch control
21 September 2006	Change of product name from 'Equipalazone Paste E-PP' to 'Equipalazone 1g Oral Paste'
30 August 2006	Change of MAH
05 April 2006	Submission of an updated Active Substance Master File (ASMF)
22 February 2006	Renewal
07 December 2001	Addition of a manufacturer of the active substance
10 February 2000	Renewal
20 July 1995	Change of safety warnings Change to formulation