

## Post Authorisation Assessments

### Equipalazone 1g Oral Paste Vm 50406/3030

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| 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.<br>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 thee 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   |

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| 02 January 2007   | Change of legal category from POM to POM-V<br>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<br>Change to formulation  |