

VPA10425/018/003

**Kelevo 800 µg tablets for dogs**

| <b>Variation</b> | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Date</b> |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Vet - B44 a)     | VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated certificate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 09/12/25    |
| Vet - B18 c)     | VNRA - Vet - B18 c) - - Vet - B18 c) -Change(s) in the composition (excipients) of the finished product — addition or replacement of a component or components of the flavouring or colouring system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 17/10/25    |
| Vet - B34        | VNRA - Vet - B34 - - Vet - B34 - Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 17/10/25    |
| Vet - C6         | VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 30/07/25    |
| Vet - A1 a)      | VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 25/07/25    |
| Vet - C10 a)     | VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 05/03/24    |
| Vet - G.I.18     | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 | 26/02/24    |
| B.II.f.1.b.1     | IB - B.II.f.1.b.1 - 1. As packaged for sale (supported by real time data) - B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 03/02/22    |