**VPA10988/109/001**

**ERADIA 125 mg/ml oral suspension for dogs**

| Variation | Summary | Date |
|---|---|---|
| Vet - A4 | VNRA - Vet - A4 - - Vet - A4 Administrative changes - Change in ATCvet Code | 21/07/26 |
| Vet - F.III.1 a) 1. | VRA-R - Vet - F.III.1 a) 1. - - Vet - F.III.1 a) 1. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where mwater is used in the last steps of the synthesis and the material is not claimed to be endotoxin free | 15/01/26 |
| Vet - B35 b) | VNRA - Vet - B35 b) - - Vet - B35 b) -Change in the specification parameters or limits of the immediate packaging of the finished product: addition of a new specification parameter to the specification with its corresponding test method | 09/01/26 |
| Vet - C6 | VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 | 03/06/25 |
| 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 | 01/07/24 |
| 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 | 08/11/23 |

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| | or Regulation (EC) No 726/2004 | |