

VPA10660/002/002

**Vitofyllin 100 mg film-coated tablets for dogs**

| <b>Variation</b> | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Date</b> |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 25/09/24    |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 08/08/23    |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 25/07/23    |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 13/07/23    |
| 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 | 12/10/22    |