

VPA10774/072/003

**Twinox 400 mg/100 mg chewable tablets for dogs**

| <b>Variation</b>     | <b>Summary</b>  | <b>Date</b> |
|----------------------|---|-------------|
| Vet - C1             | VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)   | 31/03/26    |
| Vet - B3 a)          | VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) | 29/05/25    |
| 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   | 03/05/24    |
| Vet - F.II.f.1 z)    | VRA-R - Vet - F.II.f.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.f.1 z) Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021   | 14/12/23    |
| Vet - F.II.f.1 a) 1. | VRA-R - Vet - F.II.f.1 a) 1. - a) Extension of the shelf life of the finished product 1. As packaged for sale (supported by real time data) - F.II.f.1 a) 1. Quality Changes -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)   | 14/12/23    |
| Vet - C10 c)         | VNRA - Vet - C10 c) - c) Inclusion of traceability stickers in or on product carton - C10 c) 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: — inclusion of traceability stickers in or on product carton   | 19/05/23    |