

VPA10453/002/001

AMPROLINE 400 mg/mL solution for use in drinking water for chickens and turkeys

| Variation | Summary | Date |
|-------------------|---|----------|
| Vet - C1 | VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) | 17/06/25 |
| 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 | 17/06/25 |
| Vet - F.II.d.2 b) | VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 09/04/24 |
| Vet - C1 | VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) | 22/03/24 |
| Vet - C5 | VNRA - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location - C5 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change in the pharmacovigilance system master file (PSMF) location | 22/03/24 |
| 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 | 31/10/23 |