## VPA22664/130/001

## Tauramox 5 mg/ml Pour-On Solution for Cattle

| Variation | Summary   | Date     |
|-----------|---|----------|
| Vet - C6  | VNRA - Vet - C6 - Introduction of a summary of the PSMF or<br>changes to the summary of the PSMF not already covered elsewhere<br>in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety,<br>efficacy and pharmacovigilance part of the dossier: Introduction of a<br>summary of the PSMF or changes to the summary of the PSMF not<br>already covered elsewhere in the Annex to Regulation (EU) 2021/17                                  | 25/07/23 |
| Vet - B46 | VNRA - Vet - B46 - Submission of a new or updated Ph. Eur. TSE<br>CEP for a non- sterile active substance, starting material, reagent or<br>intermediate, excipient - B46 Changes to the quality part of the<br>dossier: Submission of a new or updated Ph. Eur. TSE CEP for a non-<br>sterile: — active substance; — starting material, reagent, intermediate<br>used in the manufacturing process of the active substance; —<br>excipient           | 09/01/23 |
| Vet - C3  | VNRA - Vet - C3 - Change(s) in the SPC, labelling or package leaflet<br>of a generic or hybrid medicinal product following assessment of the<br>same change(s) for the reference product - C3 Changes to the safety,<br>efficacy and pharmacovigilance part of the dossier: Change(s) in the<br>SPC, labelling or package leaflet of a generic or hybrid medicinal<br>product following assessment of the same change(s) for the reference<br>product | 16/12/22 |