

VPA22664/140/003

**Moxiclear 250 mg + 62.5 mg spot-on solution for large dogs**

| <b>Variation</b> | <b>Summary</b>  | <b>Date</b> |
|------------------|---|-------------|
| 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   | 24/11/23    |
| Vet - B12 a)     | VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device               | 04/08/23    |
| Vet - B22        | VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product  | 04/08/23    |
| 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                     | 19/07/23    |
| Vet - B46        | VNRA - Vet - B46 - Submission of a new or updated Ph. Eur. TSE CEP for a non- sterile active substance, starting material, reagent or intermediate, excipient - B46 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. TSE CEP for a non- sterile: — active substance; — starting material, reagent, intermediate used in the manufacturing process of the active substance; — excipient | 05/01/23    |
| Vet - B46        | VNRA - Vet - B46 - Submission of a new or updated Ph. Eur. TSE CEP for a non- sterile active substance, starting material, reagent or intermediate, excipient - B46 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. TSE CEP for a non- sterile: — active substance; — starting material, reagent, intermediate used in the manufacturing process of the active substance; — excipient | 05/01/23    |