

VPA22664/140/003

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

Variation	Summary	Date
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	12/03/25
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,	05/01/23

	intermediate used in the manufacturing process of the active substance; — excipient	
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