

VPA22664/083/001

Closamectin Solution for Injection for Cattle and Sheep

Variation	Summary	Date
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	25/07/23
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	20/03/23
Vet - G.I.11 b)	VRA-R - Vet - G.I.11 b) - b) Deletion not resulting from a safety issue - G.I.11 b) Safety, Efficacy, Pharmacovigilance changes - Deletion of a food producing or non-food producing target species - Deletion not resulting from a safety issue	06/12/22
Vet - B3 t)	VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	04/08/22
B.I.z	II - B.I.z - z Other variation - B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Other variation	09/06/22