

VPA22664/073/001

**Norocarp 50 mg/ml Solution for Injection for Cattle**

Variation	Summary	Date
Vet - F.II.b.5 z)	VRA-S - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	18/12/24
Vet - F.II.e.4 b)	VRA-S - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	18/12/24
Vet - F.II.b.4 z)	VRA-S - Vet - F.II.b.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	18/12/24
Vet - F.II.b.3 a)	VRA-S - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	18/12/24
Vet - F.II.a.3 b) 5.	VRA-S - Vet - F.II.a.3 b) 5. - b) Other excipients 5. Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level - F.II.a.3 b) 5. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level	18/12/24
Vet - F.III.1 a) 1.	VRA-R - Vet - F.III.1 a) 1. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. 1. New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free - F.III.1 a) 1. Quality Changes - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability	20/08/24

	to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	
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	24/04/24
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	24/04/24
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	12/02/24
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	03/08/23