

VPA10996/238/001

Nuflor 40 mg/g Premix for Medicated Feeding Stuff for Swine

Variation	Summary	Date
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	03/03/25
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	26/06/24
Vet - F.I.b.1 z)	VRA-R - Vet - F.I.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.b.1 z) Quality Changes - Active Substance - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	12/01/24
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	14/02/23
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting	27/01/23

	material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	
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