

VPA10454/021/001

Vetmedin 5 mg capsules

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	11/06/25
Vet - F.III.1 b) 1.	VRA-S - Vet - F.III.1 b) 1. - b) European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient 1. New/updated certificate from an already- approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required - F.III.1 b) 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 TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - New/updated certificate from an already- approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required	10/06/25
Vet - B44	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	08/09/23
Vet - B4 c)	VNRA - Vet - B4 c) - c) Introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites) - B4 c)	23/08/23

	Changes to the quality part of the dossier: Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites)	
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	24/05/23
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	15/03/23