

VPA10454/021/001

**Vetmedin 5 mg capsules**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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) 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)	23/08/23
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, 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