

VPA10454/073/001

Panomec 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs

Variation	Summary	Date
Vet - B47 a)	VNRA - Vet - B47 a) - - Vet - B47 a) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State	06/08/25
Vet - B44(Do not use)	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	10/01/25
Vet - F.II.b.3 g)	VRA-S - Vet - F.II.b.3 g) - g) Move the sterilizing filtration from A/B to C - F.II.b.3 g) 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 - Move the sterilizing filtration from A/B to C	21/12/23
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
Vet - A1 e)	VNRA - Vet - A1 e) - e) Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	03/08/22