

VPA10454/068/001

Ivomec Super Injection for Cattle

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	05/08/25
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	22/07/25
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	04/04/25
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
B.I.a.1.b	II - B.I.a.1.b - b) Introduction of a manufacturer of the active substance supported by an ASMF - B.I.a.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE -	18/05/23

	<p>Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF</p>	
Vet - C1	<p>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)</p>	15/03/23
Vet - A1 e)	<p>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)</p>	04/08/22