

VPA10454/064/001

**Ivomec Classic Injection for Cattle and Sheep 10 mg/ml**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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	19/02/25
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	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 - 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)	04/08/22