

**VPA10826/023/001**

**Menbutil 100 mg/ml solution for injection for cattle, pigs, horses, sheep and goats**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
Vet - B47 c)	VNRA - Vet - B47 c) - - Vet - B47 c) -Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.	28/11/25
Vet - B3 g)	VNRA - Vet - B3 g) - - Vet - B3 g) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	24/11/25
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	06/08/25
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	22/11/24