

VPA10815/050/001

Gabbrovet 140 mg/ml solution for use in drinking water, milk or milk replacer for pre-ruminant cattle and pigs

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	31/03/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	31/03/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	16/03/26
Vet - A1 b)	VNRA - Vet - A1 b) - - Vet A1 b) Administrative changes - Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	28/08/25
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - - Vet - F.I.a.2 d) - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	27/08/25
Vet - A1 a)	VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder	25/08/25
Vet - A1 b)	VNRA - Vet - A1 b) - b) Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. - A1 b) Administratvie changes: Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	22/02/23
Vet - B4 b)	VNRA - Vet - B4 b) - b) Changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place - B4 b) Changes to the quality part of the dossier: Changes to the production process or the storage of active	22/02/23

	substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place	
Vet - B12 d)	VNRA - Vet - B12 d) - d) Minor changes in the manufacturing process of an active substance - B12 d) Changes to the quality part of the dossier: Minor changes — in the manufacturing process of an active substance	22/02/23
Vet - A1 c)	VNRA - Vet - A1 c) - c) Change in the name or address or contact details of an active substance master file (ASMF) holder - A1 c) Administrative changes: Change in the name or address or contact details of an active substance master file (ASMF) holder	22/02/23
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - B3 d) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance; — a starting material; —an intermediate or reagent used in the manufacturing process of the active substance	22/02/23
Vet - F.I.c.1 z)	VRA-R - Vet - F.I.c.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.c.1 z) Quality Changes - Active Substance - Container closure system - Change in immediate packaging of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	21/02/23
Vet - F.II.e.2 z)	VRA-R - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	04/11/22
Vet - F.II.e.1 a) 1.	VRA-R - Vet - F.II.e.1 a) 1. - a) Qualitative and quantitative composition 1. Semi-solid and non-sterile liquid pharmaceutical forms - F.II.e.1 a) 1. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Semi-solid and non-sterile liquid pharmaceutical forms	04/11/22