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 - 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 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	22/02/23
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	22/02/23

	contact details of an active substance master file (ASMF) holder - A1 c) Administratvie changes: Change in the name or address or contact details of an active substance master file (ASMF) holder	
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