VPA10846/005/001

HIPRABOVIS SOMNI/LktEmulsion for injection for cattle

Variation	Summary	Date
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - F.II.d.2 a) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol	13/05/25
Vet - F.I.a.2 b)	VRA-S - Vet - F.I.a.2 b) - b) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - F.I.a.2 b) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	13/05/25
Vet - F.I.a.4 z)	VRA-R - Vet - F.I.a.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.4 z) Quality Changes - Active Substance - Manufacture -Change to in-process tests or limits applied during the manufacture of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	13/05/25
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	31/10/24

	placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	
Vet - B3 c)	VNRA - Vet - B3 c) - c) Deletion of a non-significant in-process test during the manufacture of the active substance - B3 c) Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacture of the active substance (e.g. deletion of an obsolete in-process test)	18/04/24