

VPA10815/027/001

Gleptosil 200 mg/ml Solution for Injection

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	25/03/24
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	25/03/24
Vet - F.II.b.3 z)	VRA-S - Vet - F.II.b.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.3 z) 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	20/01/23
Vet - F.II.b.1 d)	VRA-S - Vet - F.II.b.1 d) - d) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products - F.II.b.1 d) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products	20/01/23
Vet - F.II.b.1 d)	VRA-S - Vet - F.II.b.1 d) - d) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products - F.II.b.1 d) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically	20/01/23

	manufactured) excluding biological/ immunological veterinary medicinal products	
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