

VPA10491/004/001

Buprecare 0.3 mg/ml Solution for Injection for Dogs and Cats

Variation	Summary	Date
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - - Vet - F.II.b.5 z) - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	22/09/25
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - - Vet - F.II.b.3 a) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	22/09/25
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - G.I.15 z) Safety, Efficacy, Pharmacovigilance changes - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	02/01/24
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)	12/10/23
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	12/10/23