VPA10980/018/001

Alpramil 5 mg/50 mg tablets for dogs weighing at least 0.5 kg

Variation	Summary	Date
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - - Vet - G.I.15 z) - 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 this guidance	09/01/26
Vet - F.II.f.1 a) 1.	VRA-R - Vet - F.II.f.1 a) 1. - - Vet - F.II.f.1 a) 1. - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/12/25
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	16/10/25
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	16/10/25
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	10/10/25
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 placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	18/12/24
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	25/11/24
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier:	28/06/23

	Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder’s representative	