

VPA22969/003/001

Tranquiline 35 mg/ml Oral Gel for Dogs

Variation	Summary	Date
Vet - B48	VNRA - Vet - B48 - Addition or replacement of a measuring or administration device which is not an integrated part of the primary packaging - B48 Changes to the quality part of the dossier: Addition or replacement of a measuring or administration device which is not an integrated part of the primary packaging	16/04/24
Vet - E.I	VRA-R - Vet - E.I - Changes to date of the audit to verify GMP compliance of the manufacturer of the active substance - E.I - Administrative Changes - Changes to date of the audit to verify GMP compliance of the manufacturer of the active substance (Note: this variation does not apply when the information has been otherwise transmitted to the authorities (e.g. through the so-called 'QP declaration').	06/10/23
Vet - B26 a)	VNRA - Vet - B26 a) - a) Up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form - B26 a) Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form	22/12/22
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	06/10/22
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: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	05/05/22
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: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	05/05/22