VPA10980/031/001

Dormostop 5 mg/ml solution for injection for dogs and cats

Variation	Summary	Date
Vet - B21	VNRA - Vet - B21 - - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product	31/03/26
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	31/03/26
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	18/12/25
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	03/06/25
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)	09/10/24
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	09/10/24
Vet - F.II.b.1 d)	VRA-R - 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 veterianry 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 veterianry medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products	23/05/24