

VPA22583/002/001

Isothesia 1000 mg/g inhalation vapour, liquid

Variation	Summary	Date
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - b) Other changes to a test procedure (including replacement or addition) for the active substance - F.I.b.2 b) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance	11/10/23
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)	25/11/22
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)	13/07/22
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	13/07/22
B.I.a.4.z	IB - B.I.a.4.z - z Other variation - B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other variation	05/05/22
B.I.a.2.a	IB - B.I.a.2.a - a) Minor change in the manufacturing process of the active substance - B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	05/05/22
B.I.a.2.a	IA - B.I.a.2.a - a) Minor change in the manufacturing process of the active substance - B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	05/05/22