

VPA10665/001/001

Pluset powder and solvent for solution for injection

Variation	Summary	Date
Vet - F.II.b.4 d)	VRA-R - Vet - F.II.b.4 d) - d) The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - F.II.b.4 d) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)	04/10/24
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - F.II.d.2 a) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol	26/02/24
Vet - F.I.b.2 a)	VRA-S - Vet - F.I.b.2 a) - a) Substantial change to or replacement of a biological/immunological/immunochemical test - F.I.b.2 a) 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 - Substantial change to or replacement of a biological/immunological/immunochemical test	26/02/24
Vet - F.I.b.2 a)	VRA-S - Vet - F.I.b.2 a) - a) Substantial change to or replacement of a biological/immunological/immunochemical test - F.I.b.2 a) 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 - Substantial change to or replacement of a biological/immunological/immunochemical test	26/02/24
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)	18/10/23
Vet - A1 e)	VNRA - Vet - A1 e) - e) Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or	10/07/23

	contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	
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