

VPA23174/004/001

Luteoplan 0.25 mg/ml solution for injection for cattle and horses

Variation	Summary	Date
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	10/09/25
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	19/05/25
Vet – B24 b)	VNRA - Vet – B24 b) - B24 Replacement or addition of a manufacturer responsible for b) - B24 Replacement or addition of a manufacturer responsible for b)- batch release not including batch control or testing of a sterile or non-sterile finished product.	19/05/25
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder	19/05/25
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)	02/05/25
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	07/03/25
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder	29/01/25
Vet – B24 b)	VNRA - Vet – B24 b) - B24 Replacement or addition of a manufacturer responsible for b) - B24 Replacement or addition of a manufacturer responsible for b)- batch release not including batch control or testing of a sterile or non-sterile finished product.	29/01/25
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	29/01/25
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact	19/12/24

	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)	
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	20/11/24