**VPA23174/004/001**

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

| Variation | Summary | Date |
|---|---|---|
| Vet - C1 | VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) | 25/02/26 |
| Vet - C5 | VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location | 25/02/26 |
| Vet - G.I.2 b) | VRA-S - Vet - G.I.2 b) - - Vet - G.I.2 b) - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product - Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product | 16/02/26 |
| 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) Administratvie 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) Administratvie 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 | 29/01/25 |

| | | |
|---|---|---|
| | 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. | |
| 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 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) | 19/12/24 |
| 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 |