

VPA10980/027/002

Recudon 5.0 mg/ml + 0.25 mg/ml solution for injection for horses and dogs

| Variation | Summary | Date |
|----------------------|---|----------|
| Vet - F.II.f.1 a) 1. | VRA-R - Vet - F.II.f.1 a) 1. - - Vet - F.II.f.1 a) 1. - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 11/11/25 |
| Vet - F.II.b.1 d) | VRA-R - Vet - F.II.b.1 d) - - Vet - F.II.b.1 d) - 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 veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products | 29/08/25 |
| Vet - B45 | VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient | 15/04/25 |
| 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) | 11/03/25 |
| 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 | 11/03/25 |