

VPA10810/030/001

**Prasequine 1 mg tablets for horses**

| <b>Variation</b>     | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                              | <b>Date</b> |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Vet - B12 f)         | VNRA - Vet - B12 f) - - Vet - B12 f) - Minor changes: to an in-process limit range for the finished product                                                                                                                                                                                                                                                                 | 04/08/26    |
| Vet - G.I.2 z)       | VRA-R - Vet - G.I.2 z) - - Vet - G.I.2 z) - 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance                                   | 09/03/26    |
| Vet - B44 a)         | VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated certificate                                                                                                                                         | 17/10/25    |
| Vet - F.II.f.1 a) 1. | VRA-R - Vet - F.II.f.1 a) 1. - a) Extension of the shelf life of the finished product 1. As packaged for sale (supported by real time data) - F.II.f.1 a) 1. Quality Changes -Stability - 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) | 13/12/24    |
| Vet - C10 a)         | VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative                               | 22/12/23    |