

VPA10996/227/001

Estrumate

| 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 | 17/02/26 |
| Vet - F.I.f.1 | VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier | 12/01/26 |
| Vet - F.I.f.1 | VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier | 12/01/26 |
| Vet - F.I.f.1 | VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier | 12/01/26 |
| Vet - B47 b) | VNRA - Vet - B47 b) - - Vet - B47 b) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State | 18/12/25 |
| Vet - F.II.b.3 h) | VRA-R - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate or bulk product (if applicable) | 13/05/25 |
| Vet - F.V.b 1. b) | VRA-S - Vet - F.V.b 1. b) - b) Harmonisation of the quality dossier after a SPC harmonisation procedure - F.V.b 1. b) Quality Changes - Changes to a marketing authorisation resulting from other regulatory procedures - Harmonisation of the quality dossier - Harmonisation of the quality dossier after a SPC harmonisation procedure | 08/08/24 |