

VPA10402/003/001

**FLOROLAB 100 mg/ml solution for use in drinking water for pigs**

| Variation         | Summary  | Date     |
|-------------------|--|----------|
| 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)  | 15/09/22 |
| Vet - C5          | VNRA - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location - C5 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change in the pharmacovigilance system master file (PSMF) location  | 15/09/22 |
| Vet - F.II.b.4 c) | VRA-R - Vet - F.II.b.4 c) - c) More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms of biological/immunological products - F.II.b.4 c) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical forms of biological/immunological products  | 18/07/22 |
| Vet - F.I.a.1 z)  | VRA-R - Vet - F.I.a.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.1 z) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 01/07/22 |