

VPA10988/094/001

Cyclavance 100 mg/ml oral solution for dogs and cats

| Variation | Summary | Date |
|------------------|---|-------------|
| Vet - B37 | VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product | 24/04/24 |
| Vet - G.I.18 | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 | 18/12/23 |
| Vet - B44 | VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient | 05/10/23 |