

**VPA10509/025/001**

**Cylanic 50 mg + 12.5 mg tablets for dogs and cats**

| <b>Variation</b>  | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                                                              | <b>Date</b> |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 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                                                                                                                                                                         | 30/03/26    |
| Vet - F.II.d.1 a) | VRA-S - Vet - F.II.d.1 a) - - Vet - F.II.d.1 a) - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range                                                                                                                                                                                                                    | 19/03/26    |
| Vet - F.II.a.2 a) | VRA-R - Vet - F.II.a.2 a) - - Vet - F.II.a.2 a) - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses                                                                                                                                                            | 19/03/26    |
| Vet - A1 a)       | VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder                                                                                                                                                                                                                                                                                 | 29/10/25    |
| Vet - C1          | VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)                                                                                                                                                                                                                                                                       | 11/09/25    |
| 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                                                                                                                                                                                                                                                      | 11/09/25    |
| Vet - B12 a)      | VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device | 04/06/25    |