

VPA10983/044/002

**Cefaseptin 300 mg tablets for dogs**

| 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                                                                                                                                                                                                                                                                                                                                                    | 17/08/26 |
| Vet - G.I.18          | VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004                                                                                                                                                                         | 18/05/26 |
| Vet - F.II.c.4 z)     | VRA-R - Vet - F.II.c.4 z) - - Vet - F.II.c.4 z) - Change in synthesis or recovery of a non pharmacopoeial excipient (when described in the dossier) or a novel excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance                                                                                                                                                                                                                              | 26/01/26 |
| Vet - F.II.b.3 a)     | VRA-R - Vet - F.II.b.3 a) - - Vet - F.II.b.3 a) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process                                                                                                                                                                                                                                                                      | 01/10/25 |
| 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                                                                                                                                                                                                                                                                       | 12/08/25 |
| Vet - B44(Do not use) | VNRA - Vet - B44(Do not use) - 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 | 14/07/25 |
| Vet - B28 b)          | VNRA - Vet - B28 b) - b) Addition of a new specification parameter to the specification with its corresponding test method - B28 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an excipient —addition of a new specification parameter to the specification with its corresponding test method                                                                                                                                                       | 04/03/25 |
| Vet - B3 m)           | VNRA - Vet - B3 m) - m) Deletion of a non-significant specification parameter (excipient) - B3 m) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or                                                                                                                                                                                                                           | 04/03/25 |

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|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
|              | limits of an excipient                                                                                                                                                                                                                                                                                                                                                                                |          |
| Vet - B12 b) | VNRA - Vet - B12 b) - b) Minor changes to an approved test procedure (starting material, excipient) - B12 b) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient                                                               | 04/03/25 |
| Vet - B28 a) | VNRA - Vet - B28 a) - a) Tightening of specification limits - B28 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of an excipient — tightening of specification limits                                                                                                                                                                                | 04/03/25 |
| Vet - B43    | VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible                                                                                            | 03/04/24 |
| 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)                                                                                       | 16/06/23 |
| Vet - C6     | VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 | 16/06/23 |