**VPA10516/015/001**

**OCNIL 400 mg/g powder for use in drinking water**

| Variation | Summary | Date |
|---|---|---|
| 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 | 23/10/26 |
| 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 cerificate | 09/07/25 |
| Vet - F.II.b.1 z) | VRA-R - Vet - F.II.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.1 z) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 19/06/25 |
| Vet - A1 a) | VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administratvie changes: Change in the name or address or contact details of the marketing authorisation holder | 03/07/24 |
| Vet - B44(Do not use) | 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 | 27/03/23 |
| Vet - B44(Do not use) | 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 | 30/11/22 |
| Vet - B44(Do not use) | 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 | 30/11/22 |

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| | 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 | |
| Vet - C10 a) | VNRA - Vet - C10 a) - a) Administrative information concerning the holder’s representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder’s representative | 15/11/22 |