

VPA22664/021/001

**Norodine 24 % Solution for Injection**

| <b>Variation</b>  | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Date</b> |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Vet - C9          | VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 11/06/26    |
| Vet - F.II.f.1 z) | VRA-R - Vet - F.II.f.1 z) - - Vet - F.II.f.1 z) - Change in the shelf-life or storage conditions of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 23/12/25    |
| Vet - B40         | VNRA - Vet - B40 - Replacement or addition of a supplier of packaging components or devices - B40 Changes to the quality part of the dossier: Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 03/10/24    |
| 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 | 28/06/24    |
| Vet - F.II.d.1 z) | VRA-R - Vet - F.II.d.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.d.1 z) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 14/11/23    |
| Vet - F.II.d.1 z) | VRA-R - Vet - F.II.d.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.d.1 z) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 14/11/23    |
| Vet - F.II.d.1 a) | VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 14/11/23    |

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|                     | specification parameters and/or limits of the finished product - Change outside the approved specifications limits range                                                                                                                                                                                                                                                                                                                                                                                                                |          |
| Vet - F.II.d.1 a)   | VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range                                                                                                                                                                                                                           | 14/11/23 |
| Vet - F.II.d.2 b)   | VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)                                                                                                                                                                                                                          | 14/11/23 |
| Vet - F.II.b.3 a)   | VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - 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                                                                                                                                                                                                             | 14/11/23 |
| Vet - F.II.b.3 a)   | VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - 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                                                                                                                                                                                                             | 14/11/23 |
| Vet - B30 a)        | VNRA - Vet - B30 a) - a) Tightening of specification limits - B30 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: — tightening of specification limits                                                                                                                                                                                                                                                                                                         | 13/11/23 |
| Vet - B27 b)        | VNRA - Vet - B27 b) - b) Addition of a new in-process test and limits - B27 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — addition of a new in-process test and limits                                                                                                                                                                                                                                                                  | 13/11/23 |
| Vet - C2            | VNRA - Vet - C2 - Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - C2 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 | 25/07/23 |
| 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                                                                                                                                   | 20/07/23 |
| Vet - F.III.1 a) 1. | VRA-R - Vet - F.III.1 a) 1. - a) European Pharmacopoeial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 20/06/23 |

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|             | <p>Certificate of Suitability to the relevant Ph. Eur. Monograph. 1. New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free - F.III.1 a) 1. Quality Changes - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free</p> |          |
| Vet - B3 t) | <p>VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 31/03/23 |
| Vet - B3 t) | <p>VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 30/03/23 |