

VPA10484/022/001

**Parazole Dog/Cat 100 mg/ml Oral Suspension**

| Variation         | Summary   | Date     |
|-------------------|---|----------|
| 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   | 16/05/24 |
| 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 | 06/03/24 |
| Vet - F.II.e.1 z  | VRA-R - Vet - F.II.e.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.e.1 z) Quality Changes - Container closure system - Change in immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021   | 26/02/24 |
| 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   | 26/02/24 |
| 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  | 26/02/24 |
| 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  | 26/02/24 |
| 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  | 26/02/24 |

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| 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  | 26/02/24 |
| 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  | 26/02/24 |
| Vet - F.II.b.1 c) | VRA-R - Vet - F.II.b.1 c) - c) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products - F.II.b.1 c) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products | 26/02/24 |
| Vet - F.II.e.2 z) | VRA-S - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021  | 26/02/24 |
| 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   | 19/07/23 |
| 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)   | 09/05/23 |
| Vet - B3 a)       | VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for                 | 12/12/22 |

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|     | batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)                             |          |
| A.1 | IAin - A.1 - A.1 Change in the name and/or address of the marketing authorisation holder - A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder | 11/03/22 |