

VPA10826/001/001

**Calcitat 25, solution for infusion and injection in cattle**

| Variation         | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Date     |
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| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 11/07/25 |
| 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                                                                                                                                                                                                                                                                                                                                                                                   | 17/07/24 |
| Vet - F.II.e.5 a) | VRA-R - Vet - F.II.e.5 a) - a) Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes - F.II.e.5 a) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes                                                                                                                                                                                                                                                                                                                                                                                            | 29/01/24 |
| Vet - F.II.d.1 b) | VRA-S - Vet - F.II.d.1 b) - b) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product - F.II.d.1 b) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product                                                                                                                                                                                                                                                                                                                                               | 22/01/24 |
| Vet - F.II.b.1 d) | VRA-S - Vet - F.II.b.1 d) - d) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products - F.II.b.1 d) 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, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products | 02/12/23 |
| 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,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 27/11/23 |

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|                       | <p>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)</p> <p>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 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)</p> |          |
| Vet - B21             | <p>VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21</p> <p>Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product</p>                                                                                                                                                                                                                                                                                              | 27/11/23 |
| Vet - B22             | <p>VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22</p> <p>Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product</p>                                                                                                                                                                                          | 27/11/23 |
| Vet - B24(Do not use) | <p>VNRA - Vet - B24 - Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product - B24</p> <p>Changes to the quality part of the dossier: Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product</p>                                                                                                                                                           | 27/11/23 |
| Vet - F.II.d.2 b)     | <p>VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b)</p> <p>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)</p>                                                                                                                                                                                                            | 07/06/23 |
| Vet - F.II.d.2 b)     | <p>VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b)</p> <p>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)</p>                                                                                                                                                                                                            | 21/04/23 |
| Vet - F.II.d.2 b)     | <p>VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b)</p> <p>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)</p>                                                                                                                                                                                                            | 21/04/23 |
| Vet - F.II.c.1 z)     | <p>VRA-S - Vet - F.II.c.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.c.1 z)</p> <p>Quality Changes - Finished Product -Control of excipients-Change in the</p>                                                                                                                                                                                                                                                                                                | 21/04/23 |

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|                       | specification parameters and/or limits of an excipient -<br>Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021                                                                                                                                                                                                                                                                                                                            |          |
| Vet - B3 n)           | VNRA - Vet - B3 n) - n) Deletion of a non-significant specification parameter (finished product) - B3 n)<br>Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product                                                                                | 27/09/22 |
| 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 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 | 19/07/22 |
| 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 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 | 04/07/22 |