**VPA22020/009/002**

**MILBEMAX film-coated tablets for cats**

| Variation | Summary | Date |
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| Vet - B3 t) | VNRA - Vet - B3 t) - - Vet - 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 | 15/12/25 |
| Vet - B12 a) | VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient | 06/08/25 |
| Vet - F.II.d.2 b) | VRA-R - Vet - F.II.d.2 b) - - Vet - F.II.d.2 b) - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 06/08/25 |
| Vet - B26 c) | VNRA - Vet - B26 c) - c) Downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form - B26 c) Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form | 12/02/25 |
| Vet - F.II.b.3 h) | VRA-S - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) 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 - Change in the holding time of an intermediate or bulk product (if applicable) | 11/02/25 |
| Vet - F.I.b.1 d) | VRA-R - Vet - F.I.b.1 d) - d) Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue - F.I.b.1 d) Quality Changes - Active Substance - Control of active substance -Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue | 14/01/25 |
| Vet - C9 | VNRA - Vet - C9 - Editorial changes to SPC, package | 10/01/25 |

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| | leaflet or labelling if inclusion in an upcoming procedure is not possible - C9 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible | |
| 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) | 22/11/24 |
| 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 | 22/11/24 |
| 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 | 13/06/24 |
| 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 | 11/06/24 |
| 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 | 27/09/23 |

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| | 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 | |
| Vet - B12 a) | VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng 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 | 24/08/23 |
| 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 | 17/07/23 |