VPA10988/096/001

Milpro 4 mg/10 mg film-coated tablets for small cats and kittens

| Variation | Summary | Date |
|---------------------|--|----------|
| 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 | 03/06/25 |
| Vet - F.III.1 a) z. | VRA-R - Vet - F.III.1 a) z a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. Quality Changes - CEP/TSE/MONOGRAPHS -Submission of a new or updated Ph. Eur. certificate of suitability or deletion of | 06/01/25 |
| Vet - F.III.1 a) z. | VRA-R - Vet - F.III.1 a) z a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 06/01/25 |
| Vet - F.III.1 a) z. | VRA-R - Vet - F.III.1 a) z a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. 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 - Other changes under this code | 06/01/25 |

| | level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | |
|---------------------|---|----------|
| Vet - F.III.1 a) z. | VRA-R - Vet - F.III.1 a) z a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. Quality Changes - CEP/TSE/MONOGRAPHS -Submission of a new or updated Ph. Eur. certificate of suitability or deletion of | 06/01/25 |
| Vet - B3 i) | VNRA - Vet - B3 i) - i) Deletion of a component or components of the flavouring or colouring system - B3 i) Changes to the quality part of the dossier: Deletion of a component or components of the flavouring or colouring system | 21/10/24 |
| Vet - F.II.c.1 z) | VRA-R - 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) Quality Changes - Finished Product -Control of excipients-Change in the specification parameters and/or limits of an excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 09/12/22 |
| Vet - F.II.c.4 z) | VRA-R - Vet - F.II.c.4 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.4 z) Quality Changes - Finished Product -Control of excipients-Change in synthesis or recovery of a non- pharmacopoeial excipient (when described in the dossier) or a novel excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 09/12/22 |