**VPA10475/017/001**

**Furosoral 10 mg tablets for cats and dogs**

| Variation | Summary | Date |
|---|---|---|
| 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 | 08/01/24 |
| Vet - F.II.b.3 h) | VRA-R - 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) | 08/01/24 |
| 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 | 08/01/24 |
| 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 | 08/01/24 |
| Vet - B32 | VNRA - Vet - B32 - Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product - B32 Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product | 02/01/24 |
| Vet - B21 | VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product | 02/01/24 |
| Vet - B20 | VNRA - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product - B20 Changes to the quality part of the dossier: Replacement or addition of a primary packaging site of a non-sterile finished product | 02/01/24 |
| Vet - B34 | VNRA - Vet - B34 - Change in qualitative and quantitative composition of the immediate packaging for a solid | 02/01/24 |

| | | |
|---|---|---|
| | pharmaceutical form for a finished product - B34 Changes to the quality part of the dossier: Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product | |
| Vet – B24 a) | VNRA - Vet – B24 a) - B24 Replacement or addition of a manufacturer responsible for a) - B24 Replacement or addition of a manufacturer responsible for a)- batch release including batch control or testing of a sterile or non-sterile finished product | 02/01/24 |
| Vet - B26 a) | VNRA - Vet - B26 a) - a) Up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form - B26 a) Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form | 02/01/24 |
| 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 | 24/04/23 |
| Vet - B47 c) | VNRA - Vet - B47 c) - c) Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. - B47 c) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. | 24/04/23 |