**VPA10823/010/001**

**Levapharm Injection 75 mg/ml**

| Variation | Summary | Date |
|---|---|---|
| Vet - F.II.e.1 b) 2. | VRA-S - Vet - F.II.e.1 b) 2. - - Vet - F.II.e.1 b) 2. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products | 21/05/26 |
| Vet - F.II.b.5 z) | VRA-R - Vet - F.II.b.5 z) - - Vet - F.II.b.5 z) - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance | 21/05/26 |
| Vet - F.II.b.4 z) | VRA-R - Vet - F.II.b.4 z) - - Vet - F.II.b.4 z) - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance | 21/05/26 |
| Vet - F.II.b.1 z) | VRA-R - Vet - F.II.b.1 z) - - Vet - F.II.b.1 z) - 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 this guidance | 21/05/26 |
| Vet - B32 | VNRA - Vet - B32 - - Vet - B32 - Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product | 21/05/26 |
| Vet - B32 | VNRA - Vet - B32 - - Vet - B32 - Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product | 21/05/26 |
| Vet - B43 | VNRA - Vet - B43 - - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible | 21/05/26 |
| Vet - A1 c) | VNRA - Vet - A1 c) - - Vet - A1 c) Administrative changes - c) Change in the name or address or contact details of an active substance master file (ASMF) holder | 15/05/26 |
| Vet - B47 a) | VNRA - Vet - B47 a) - - Vet - B47 a) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State | 15/05/26 |
| 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, | 09/09/24 |

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|---|---|---|
| | 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 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 | |