

VPA22020/003/001

**Fasinex 240 mg/ml oral suspension for cattle**

Variation	Summary	Date
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.a.3 a) Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	19/05/25
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 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	06/03/25
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 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	05/02/25
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	30/06/23
Vet - B27 b)	VNRA - Vet - B27 b) - b) Addition of a new in-process test and limits - B27 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — addition of a new in-process test and limits	08/02/23
Vet - B27 b)	VNRA - Vet - B27 b) - b) Addition of a new in-process test and limits - B27 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — addition of a new in-process test and limits	31/01/23

Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - 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 EMA/CMDv/7381/2021	11/10/22
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.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.b.4 z) Quality Changes - Finished Product -Manufacture - 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 EMA/CMDv/7381/2021	11/10/22
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 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	13/07/22