VPA22020/003/001

Fasinex 240 mg/ml oral suspension for cattle

Variation	Summary	Date
Vet - C9	VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	15/07/26
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	18/11/25
Vet - B35 b)	VNRA - Vet - B35 b) - - Vet - B35 b) -Change in the specification parameters or limits of the immediate packaging of the finished product: addition of a new specification parameter to the specification with its corresponding test method	18/11/25
Vet - F.IV.1 a) 1.	VRA-R - Vet - F.IV.1 a) 1. - - Vet - F.IV.1 a) 1. - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking	23/10/25
Vet - F.II.e.1 b) 1.	VRA-R - Vet - F.II.e.1 b) 1. - - Vet - F.II.e.1 b) 1. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	23/10/25
Vet - F.II.e.4 a)	VRA-S - Vet - F.II.e.4 a) - - Vet - F.II.e.4 a) - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product	23/10/25
Vet - F.II.e.1 a) 1.	VRA-R - Vet - F.II.e.1 a) 1. - - Vet - F.II.e.1 a) 1. - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	23/10/25
Vet - F.II.e.4 a)	VRA-S - Vet - F.II.e.4 a) - - Vet - F.II.e.4 a) - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product	23/10/25
Vet - B44 a)	VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated cerificate	09/09/25
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 -	19/05/25

	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	
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(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	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	11/10/22

	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	
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