

VPA10987/142/002

Albex 10 % Oral Suspension

Variation	Summary	Date
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	28/08/26
Vet - B33 b)	VNRA - Vet - B33 b) - - Vet - B33 b) - Change in test procedure for the finished product to comply with Ph. Eur.: update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method numbe	19/08/26
Vet - B12 a)	VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient	19/08/26
Vet - B12 h)	VNRA - Vet - B12 h) - - Vet - B12 h) - Minor changes: to production equipment (when described in the dossier) including processes related to the equipment	19/08/26
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	19/08/26
Vet - B33 b)	VNRA - Vet - B33 b) - - Vet - B33 b) - Change in test procedure for the finished product to comply with Ph. Eur.: update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method numbe	19/08/26
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	18/09/24
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	26/10/23

Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	21/06/23
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	21/06/23
B.I.z	II - B.I.z - z Other variation - B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Other variation	07/03/22