VPA22622/007/001

Equipalazone 1 g Oral Paste

Variation	Summary	Date
Vet - B31	VNRA - Vet - B31 - - Vet - B31 - Uniformity of dosage units is introduced to replace the currently registered method	23/10/25
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	11/12/24
Vet - B33 a)	VNRA - Vet - B33 a) - a) Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - B33 a) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test procedure to comply with the updated general monograph in the Ph. Eur.	30/08/23
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	30/08/23
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	31/01/23
Vet - B18 c)	VNRA - Vet - B18 c) - c) Addition or replacement of a component or components of the flavouring or colouring system - B18 c) Changes to the quality part of the dossier: Change(s) in the composition (excipients) of a non-sterile finished product —addition or replacement of a component or components of the flavouring or colouring system	16/01/23
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	08/07/22

	changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	
Vet - C9	VNRA - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible - C9 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	08/07/22