

VPA22664/024/001

Levafas Diamond Fluke and Worm Drench

Variation	Summary	Date
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	23/04/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	04/03/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	04/03/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	04/03/24
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	28/08/23
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	20/07/23

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	02/05/23
Vet - C4	VNRA - Vet - C4 - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - C4 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products	09/03/23
Vet - A1 c)	VNRA - Vet - A1 c) - c) Change in the name or address or contact details of an active substance master file (ASMF) holder - A1 c) Administrative changes: Change in the name or address or contact details of an active substance master file (ASMF) holder	30/06/22
Vet - B47 a)	VNRA - Vet - B47 a) - a) 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 - B47 a) Changes to the quality part of the dossier: 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	30/06/22