VPA10203/001/001

Winter Dip Concentrate for dip emulsion

Variation	Summary	Date
Vet - B40	VNRA - Vet - B40 - - Vet - B40 - Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)	22/07/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	28/05/26
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - - Vet - F.I.b.2 b) - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate	19/01/26
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	23/06/25
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - a) Introduction of a manufacturer of the active substance supported by an ASMF - F.I.a.1 a) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF	10/06/25
Vet - F.II.e.5 c)	VRA-R - Vet - F.II.e.5 c) - c) Change in the fill weight/fill volume of non- parenteral multi-dose (or single-dose, partial use) products - F.II.e.5 c) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the fill weight/fill volume of non- parenteral multi-dose (or single-dose, partial use) products	02/05/24
B.II.a.3.b.2	II - B.II.a.3.b.2 - 2. Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the medicinal product - B.II.a.3.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the	05/01/23

	medicinal product	