VPA10555/003/002

Orafluke 10 % w/v Oral Suspension

Variation	Summary	Date
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	20/08/26
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	07/11/25
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	26/03/25
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	05/11/24
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	20/05/24
Vet - B45	VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	15/01/24

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	08/11/23
Vet - F.II.e.1 z	VRA-R - Vet - F.II.e.1 z - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.1 z) Quality Changes - Container closure system - Change in immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	20/12/22