VPA10454/037/001

EQVALAN Oral Paste for Horses 18.7 mg/g

Variation	Summary	Date
	VRA-R - Vet - F.II.d.2 b) Vet - F.II.d.2 b) - Change in	
Vet - F.II.d.2 b)	test procedure for the finished product - Other changes to	25/08/25
	a test procedure (including replacement or addition)	
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	10/01/25
	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	
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product	15/11/24
	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	
	VNRA - Vet - A1 e) - e) Change in the name or address or	
Vet - A1 e)	contact details of a manufacturer or importer of the	
	finished product (including batch release or quality	
	control testing sites) - A1 e) Administrative changes:	14/08/23
	Change in the name or address or contact details of a	11/00/23
	manufacturer or importer of the finished product	
	(including batch release or quality control testing sites)	
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,	1.5/02/22
	efficacy and pharmacovigilance part of the dossier:	15/03/23
	Change(s) in the name or address or contact details of a	
	qualified person for pharmacovigilance (QPPV)	
Vot. A1 a)	VNRA - Vet - A1 e) - e) Change in the name or address or	12/00/22
Vet - A1 e)	contact details of a manufacturer or importer of the	12/08/22

finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or contact details of a	
manufacturer or importer of the finished product	
(including batch release or quality control testing sites)	