VPA22033/060/001

Endofluke 100 mg/ml Oral Suspension

Variation	Summary	Date
Vet - B44	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	19/09/23
Vet - B44	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	19/09/23
Vet - B44	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	19/09/23
Vet - B44	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	18/09/23
Vet - B44	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	18/09/23
Vet - B44	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	18/09/23

	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 - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements	
	and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to	13/03/23
	importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35 a)	09/06/22
	Changes to the quality part of the dossier: Change in the	
	specification parameters or limits of the immediate packaging of the finished product: — tightening of specification limits	
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35 a)	
	Changes to the quality part of the dossier: Change in the	08/06/22
	specification parameters or limits of the immediate packaging of the	
	finished product: — tightening of specification limits	