

VPA10784/003/001

Entericolix, emulsion for injection for pigs

Variation	Summary	Date
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	02/10/23
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	01/08/23
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administratieve changes: Change in the name or address or contact details of the marketing authorisation holder	05/05/23
Vet - A1 b)	VNRA - Vet - A1 b) - b) Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. - A1 b) Administratieve changes: Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	05/05/23
Vet - A1 e)	VNRA - Vet - A1 e) - e) 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) - 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)	05/05/23
Vet - F.I.a.4 a)	VRA-S - Vet - F.I.a.4 a) - a) Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the active substance - F.I.a.4 a) Quality Changes - Active Substance - Manufacture -Change to in-process tests or limits applied during the manufacture of the active substance - Widening of the approved in-process test limits, which may have	17/02/23

	a significant effect on the overall quality of the active substance	
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