

VPA10826/016/001

Enrotron 5 mg/ml oral solution for pigs

Variation	Summary	Date
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	25/07/25
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	11/04/24
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	04/12/23
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	04/12/23