

VPA10826/026/003

Enrotron 100 mg/ml Solution for injection for cattle, sheep, goats and pigs

Variation	Summary	Date
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	31/10/23
Vet - G.I.1 a)	VRA-R - Vet - G.I.1 a) - a) The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH - G.I.1 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH	12/09/22