VPA10402/008/001

Labimycin LA 300 mg/ml solution for injection

Variation	Summary	Date
Vet - G.I.2 a)	VRA-S - Vet - G.I.2 a) - - Vet - G.I.2 a) - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)	03/02/26
Vet - G.I.17 b)	VRA-R - Vet - G.I.17 b) - - Vet - G.I.17 b) - Changes in relation to MR/SR procedures - Adaptation of the Product Information for the original Concerned Member States after a SRP	03/02/26
Vet - C10 a)	VNRA - Vet - C10 a) - - Vet - C10 a) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: administrative information concerning the holder's representative	22/01/26
Vet - B44(Do not use)	VNRA - Vet - B44(Do not use) - 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	18/07/25
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	07/05/25
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	20/02/25