

VPA10454/013/001

Sedivet 10 mg/ml Solution for Injection for horses

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	15/03/23
Vet - B41 a)	VNRA - Vet - B41 a) - a) Reduction of the shelf life of the finished product as packaged for sale, after first opening or after dilution or reconstitution - B41 a) Changes to the quality part of the dossier: Change in the shelf-life or to an approved stability protocol of the finished product: — reduction of the shelf life of the finished product as packaged for sale, after first opening or after dilution or reconstitution	26/07/22
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	30/03/22