

VPA10816/006/003

**Floxabactin 150 mg tablets for dogs**

Variation	Summary	Date
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	13/12/23
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - F.II.d.2 a) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol	13/12/23
Vet - B31	VNRA - Vet - B31 - Uniformity of dosage units is introduced to replace the currently registered method - B31 Changes to the quality part of the dossier: Uniformity of dosage units is introduced to replace the currently registered method	21/06/22