VPA10555/005/001

Sulphamet 40/200 Solution for Injection

Variation	Summary	Date
Vet - F.II.e.5 a)	VRA-R - Vet - F.II.e.5 a) - a) Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes - F.II.e.5 a) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes	15/07/25
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	15/08/24
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	15/08/24
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	22/03/24
Vet - C2	VNRA - Vet - C2 - Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet	02/11/23

	intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - C2 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6	