VPA10989/070/001

Diatrim 200 mg/ml + 40 mg/ml solution for injection

Variation	Summary	Date
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	08/01/24
Vet - G.I.1 z)	VRA-R - Vet - G.I.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - G.I.1 z) 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	08/01/24
Vet - F.II.e.5 b)	VRA-S - Vet - F.II.e.5 b) - b) Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products. - F.II.e.5 b) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products.	08/01/24
Vet - F.II.e.1 a) 2.	VRA-S - Vet - F.II.e.1 a) 2. - a) Qualitative and quantitative composition 2. Sterile medicinal products and biological/immunological medicinal products. - F.II.e.1 a) 2. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products.	08/01/24
Vet - B44	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,	22/12/22

	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	
Vet - B45	VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	22/12/22