

VPA10981/001/001

**Co-Trimoxazole 24% w/v solution for injection**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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, 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	07/03/25
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	03/01/25
Vet - F.II.f.1 a) 2.	VRA-R - Vet - F.II.f.1 a) 2. - a) Extension of the shelf life of the finished product 2. After first opening (supported by real time data) - F.II.f.1 a) 2. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data)	11/06/24
Vet - F.II.b.4 b)	VRA-S - Vet - F.II.b.4 b) - b) The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes - F.II.b.4 b) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	11/06/24
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.a.3 a) Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	11/06/24
Vet - F.II.f.1 c)	VRA-R - Vet - F.II.f.1 c) - c) Change in storage conditions of the finished product or the diluted/reconstituted product - F.II.f.1 c) Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product	11/06/24
Vet - B30 d)	VNRA - Vet - B30 d) - d) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product - B30 d) Changes to the quality part of the dossier: Change in the specification parameters or limits of	30/01/24

	the finished product: — update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	16/01/24
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	11/12/23
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, 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	24/11/23
Vet - C2	VNRA - Vet - C2 - 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 - 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	16/06/23
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	09/06/23
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information	12/08/22

	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	
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