

VPA10988/116/001

Itrafungol 10 mg/ml Oral Solution

Variation	Summary	Date
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	03/06/25
Vet - G.I.19	VRA-R - Vet - G.I.19 - G.I.19 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6 - G.I.19 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6	19/09/24
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	13/07/23
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	09/02/23
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	15/12/22
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning	06/12/22

	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	
B.III.1.a.2	IA - B.III.1.a.2 - 2. Updated certificate from an already approved manufacturer - B.III.1.a.2 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/02/22