VPA10988/114/001

Optomease Vet 200 mg/ml concentrate for solution for fish treatment

Variation	Summary	Date
Vet - C10 a)	VNRA - Vet - C10 a) - - Vet - C10 a) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: administrative information concerning the holder's representative	23/01/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	22/12/25
Vet - A1 e)	VNRA - Vet - A1 e) - - Vet - A1 e) Administrative changes - Change in the name or address of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	24/11/25
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 - F.II.f.1 a) 1.	VRA-R - Vet - F.II.f.1 a) 1. - a) Extension of the shelf life of the finished product 1. As packaged for sale (supported by real time data) - F.II.f.1 a) 1. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	25/03/25
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	09/01/23
Vet - B24(Do not use)	VNRA - Vet - B24 - Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product - B24 Changes to the quality part of the dossier: Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product	09/01/23
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test	03/01/23

	method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	
Vet - F.II.e.1 b) 1.	VRA-R - Vet - F.II.e.1 b) 1. - b) Change in type of container or addition of a new container 1. Solid, semi-solid and non-sterile liquid pharmaceutical forms - F.II.e.1 b) 1. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms immunological medicinal products	17/08/22