

VPA22033/059/001

Ectofly 12.5 mg/ml Pour-On Solution for Sheep

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	28/07/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	28/07/26
Vet - B24 a)	VNRA - Vet - B24 a) - - Vet - B24 a) - Replacement or addition of a manufacturer responsible for: batch release including batch control or testing of a sterile or non-sterile finished product	13/07/26
Vet - B21	VNRA - Vet - B21 - - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product	13/07/26
Vet - B26 c)	VNRA - Vet - B26 c) - - Vet - B26 c) - Change in the batch size (including batch size ranges) of the finished product: downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form	13/07/26
Vet - F.II.b.1 c)	VRA-R - Vet - F.II.b.1 c) - - Vet - F.II.b.1 c) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	13/07/26
Vet - B20	VNRA - Vet - B20 - - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product	03/07/26
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	17/07/25
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits	14/02/24

	applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - B3 k)	VNRA - Vet - B3 k) - k) Deletion of a non-significant in-process test (finished product manufacture) - B3 k) Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	26/10/23
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	06/03/23
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the immediate packaging of the finished product: — tightening of specification limits	15/12/22