VPA10774/067/003

Imoxicate 250 mg/62.5 mg spot-on solution for large dogs

Variation	Summary	Date
Vet - B12 a)	VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient	16/07/25
Vet - B3 a)	VNRA - Vet - B3 a) - - Vet - B3 a) - Changes to the quality part of the dossier - Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for importation, manufacturer responsible for batch release, site where batch control takes place, or supplier of (1) a starting material for an active substance, (2) a reagent or (3) an excipient (when mentioned in the dossier)	07/07/25
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)	07/07/25
Vet - B44(Do not use)	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	10/06/25
Vet - B44(Do not use)	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	10/06/25
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	19/03/24
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph.	13/02/24

	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	
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)	02/12/23
Vet - B12 c)	VNRA - Vet - B12 c) - c) Minor changes to an approved test procedure for an in-process test - B12 c) Changes to the quality part of the dossier: Minor changes — to an approved test procedure for an in-process test — for active substance; — for the finished product	27/03/23
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	03/03/23
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	03/03/23