VPA10481/001/001

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Variation	Summary	Date
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	30/03/26
Vet - B44 a)	VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated cerificate	23/12/25
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	26/07/24
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	15/05/24
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng 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	08/04/24
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	25/04/23
C.I.9.c	IA - C.I.9.c - c) Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system (e.g. change of the major storage/archiving	23/12/22

	location, administrative changes) - C.I.9.c - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to an existing pharmacovigilance system as described in the detailed description of the pharmacovigilance system (DDPS) - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system (e.g. change of the major storage/archiving location, administrative changes)	
A.1	IAin - A.1 - A.1 Change in the name and/or address of the marketing authorisation holder - A.1 - ADMINISTRATIVE CHANGES - Change in the name and/or address of the marketing authorisation holder	23/12/22
Vet - G.I.6 b)	VRA-S - Vet - G.I.6 b) - b) All other legal status changes - G.I.6 b) Safety, Efficacy, Pharmacovigilance changes - Change in the legal status of a medicinal product for centrally authorised products - All other legal status changes	28/09/22