

VPA10481/001/001

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Variation	Summary	Date
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring 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	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 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)	23/12/22
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