

VPA10402/005/001

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses

Variation	Summary	Date
Vet - G.I.17 b)	VRA-R - Vet - G.I.17 b) - - Vet - G.I.17 b) - Changes in relation to MR/SR procedures - Adaptation of the Product Information for the original Concerned Member States after a SRP	09/03/26
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	17/12/25
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)	29/05/25
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	06/01/25
Vet - G.I.17 a)	VRA-S - Vet - G.I.17 a) - a) Update of the dossier in preparation of a SRP/MRP/duplicate application in order to conform to the current legislation - G.I.17 a) Safety, Efficacy, Pharmacovigilance changes - Changes in relation to MR/SR procedures - Update of the dossier in preparation of a SRP/MRP/duplicate application in order to conform to the current legislation	05/05/23
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	05/05/23
C.I.z	IB - C.I.z - z Other variation - C.I.z - SAFETY, EFFICACY,	28/01/22

	PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Other variation	
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