

VPA10786/007/001

Halofusol 0.5 mg/ml oral solution for calves

Variation	Summary	Date
Vet - B26 a)	VNRA - Vet - B26 a) - - Vet - B26 a) - Change in the batch size (including batch size ranges) of the finished product: up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form	20/07/26
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	30/04/26
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	27/03/26
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - G.I.15 z) Safety, Efficacy, Pharmacovigilance changes - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	19/11/24
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	13/11/24
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	02/09/24