VPA10836/008/001

CONTINENCE 40 mg/ml syrup for dogs

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	07/10/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	07/10/26
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	30/01/26
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	19/06/25
Vet - F.II.e.4 z)	VRA-R - Vet - F.II.e.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.4 z) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	30/04/25
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	08/11/24
Vet - F.II.e.4 z)	VRA-R - Vet - F.II.e.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.4 z) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Other changes	08/11/24

	under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	08/11/24