

VPA10475/019/002

Carporal 160 mg tablets for dogs

Variation	Summary	Date
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	09/04/24
Vet - B12 e)	VNRA - Vet - B12 e) - e) Minor changes in synthesis or recovery of a non-pharmacopoeial excipient or a novel excipient - B12 e) Changes to the quality part of the dossier: Minor changes —in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier) or a novel excipient	08/04/24
Vet - B20	VNRA - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product - B20 Changes to the quality part of the dossier: Replacement or addition of a primary packaging site of a non-sterile finished product	08/04/24
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	08/04/24
Vet – B24 a)	VNRA - Vet – B24 a) - B24 Replacement or addition of a manufacturer responsible for a) - B24 Replacement or addition of a manufacturer responsible for a)- batch release including batch control or testing of a sterile or non-sterile finished product	08/04/24
Vet - F.II.b.3 h)	VRA-R - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate or bulk product (if applicable)	03/04/24
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other	03/04/24

	changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/04/24
Vet - F.II.b.1 c)	VRA-R - Vet - F.II.b.1 c) - c) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products - F.II.b.1 c) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	03/04/24