VPA10989/059/004

Cardisure flavoured 10 mg Tablets For dogs

Variation	Summary	Date
Vet - B9 a)	VNRA - Vet - B9 a) - - Vet - B9 a) - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance up to 10-fold increase compared to the originally approved batch size	15/12/25
Vet - B12 d)	VNRA - Vet - B12 d) - - Vet - B12 d) - Minor changes: in the manufacturing process of an active substance	15/12/25
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	15/12/25
Vet - B3 a)	VNRA - Vet - B3 a) - - Vet - B3 a) - Changes to the quality part of the dossier - Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for importation, manufacturer responsible for batch release, site where batch control takes place, or supplier of (1) a starting material for an active substance, (2) a reagent or (3) an excipient (when mentioned in the dossier)	15/12/25
Vet - B11 a)	VNRA - Vet - B11 a) - - Vet - B11 a) Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance for all veterinary medicinal products including products subject to Official Control Authority Batch Release (OCABR);	15/12/25
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - - Vet - F.I.a.2 d) - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	24/11/25
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	16/07/25

	Regulation (EC) No 726/2004	
B.II.b.3.a	IA - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - 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 - Minor change in the manufacturing process	03/03/22