VPA10815/034/003

Kesium 200 mg / 50 mg Chewable tablets for dogs

Variation	Summary	Date
Vet - G.I.2 b)	VRA-S - Vet - G.I.2 b) - - Vet - G.I.2 b) - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product - Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product	30/09/26
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)	22/07/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	31/03/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	31/03/26
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - - Vet - F.III.1 a) z. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	01/09/25
Vet - A1 a)	VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder	25/08/25
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - - Vet - F.I.b.2 b) - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate	29/07/25
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	19/07/24

	(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	
Vet - B3 k)	VNRA - Vet - B3 k) - k) Deletion of a non-significant in-process test (finished product manufacture) - B3 k) Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	06/06/23
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.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	02/03/23