VPA10987/135/001

Milbetab 12.5 mg/125 mg Tablets for Dogs

Variation	Summary	Date
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	30/03/26
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - - Vet - G.I.15 z) - 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 this guidance	02/01/26
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - - Vet - F.II.d.1 a) - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	15/09/25
Vet - F.II.f.1 a) 4.	VRA-S - Vet - F.II.f.1 a) 4. - - Vet - F.II.f.1 a) 4. - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - Extension of the shelf-life based on extrapolation of stability data not in accordance with VICH guidelines	15/09/25
Vet - F.II.b.3 h)	VRA-R - Vet - F.II.b.3 h) - - Vet - F.II.b.3 h) - 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)	15/09/25
Vet - F.II.e.1 z	VRA-R - Vet - F.II.e.1 z - - Vet - F.II.e.1 z) - Change in immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	15/09/25
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - - Vet - F.II.b.3 a) - 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	15/09/25
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - - Vet - F.II.d.2 b) - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	15/09/25
Vet - F.II.a.z	VRA-R - Vet - F.II.a.z - - Vet - F.II.a.z - Description and composition - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	15/09/25
Vet - F.II.a.3 b) 5.	VRA-R - Vet - F.II.a.3 b) 5. - - Vet - F.II.a.3 b) 5. - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics	15/09/25

	and at a similar level	
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	02/09/25
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	02/09/25