VPA10815/043/001

Modulis 100 mg/ml oral solution 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)	09/04/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	09/04/26
Vet - B48	VNRA - Vet - B48 - - Vet - B48 - Addition or replacement of a measuring or administration device which is not an integrated part of the primary packaging	20/03/26
Vet - C10 e)	VNRA - Vet - C10 e) - - Vet - C10 e) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: Alignment of the labelling of the immediate packaging with the requirements laid down in Article 12 of Regulation (EU) 2019/6	20/03/26
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	23/09/25
Vet - B45	VNRA - Vet - B45 - - Vet - B45 - no longer applicable	23/09/25
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - - Vet - F.II.b.1 z) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	23/09/25
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	23/09/25
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	23/09/25
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 - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	31/07/25

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	29/07/25
Vet – B24 b)	VNRA - Vet – B24 b) - B24 Replacement or addition of a manufacturer responsible for b) - B24 Replacement or addition of a manufacturer responsible for b)- batch release not including batch control or testing of a sterile or non-sterile finished product.	07/04/25
Vet - F.II.f.1 z)	VRA-R - Vet - F.II.f.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.f.1 z) Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	17/10/23
Vet - B3 t)	VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	21/12/22
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	21/12/22
B.II.d.1.e	II - B.II.d.1.e - e) Change outside the approved specifications limits range - B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	25/07/22
B.II.d.1.g	IB - B.II.d.1.g - g) Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue - B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue	25/07/22

B.II.d.1.g	IB - B.II.d.1.g - g) Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue - B.II.d.1.g - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue	25/07/22