VPA10388/001/001

API-Bioxal, 886 mg/g powder for in-hive use

Variation	Summary	Date
Vet - F.II.e.5 c)	VRA-R - Vet - F.II.e.5 c) - - Vet - F.II.e.5 c) - Change in pack size of the finished product - Change in the fill weight/fill volume of non parenteral multi dose (or single-dose, partial use) products	03/11/25
Vet - F.II.d.1 b)	VRA-S - Vet - F.II.d.1 b) - - Vet - F.II.d.1 b) - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	03/11/25
Vet - F.II.d.1 b)	VRA-S - Vet - F.II.d.1 b) - - Vet - F.II.d.1 b) - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	03/11/25
Vet - F.II.b.3 b)	VRA-S - Vet - F.II.b.3 b) - - Vet - F.II.b.3 b) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	03/11/25
Vet - F.II.a.3 b) 1.	VRA-S - Vet - F.II.a.3 b) 1. - - Vet - F.II.a.3 b) 1. - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product	03/11/25
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	06/08/25
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	06/08/25
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	18/11/24

	placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	