

VPA22693/012/001

Tizoval 6 mg/g Premix for medicated feeding stuff for pigs

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	19/08/26
Vet - F.II.c.1 a)	VRA-S - Vet - F.II.c.1 a) - - Vet - F.II.c.1 a) - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	05/06/26
Vet - F.III.2 z)	VRA-R - Vet - F.III.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.2 z) Quality Changes - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	19/12/25
Vet - B47 b)	VNRA - Vet - B47 b) - - Vet - B47 b) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	26/06/25
Vet - A2	VNRA - Vet - A2 - Change in the (invented) name of the veterinary medicinal product - A2 Administrative changes: Change in the (invented) name of the veterinary medicinal product	24/03/25
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	06/03/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	13/12/24
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	28/08/24

Vet - F.II.b.3 h)	VRA-R - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) 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 - Change in the holding time of an intermediate or bulk product (if applicable)	16/11/23
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