VPA10665/003/001

VETERELIN 0.004 mg/ml solution for injection for cattle, horses, pigs and rabbits

Variation	Summary	Date
Vet - C10 a)	VNRA - Vet - C10 a) - - Vet - C10 a) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: administrative information concerning the holder's representative	25/08/26
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	19/03/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	11/03/26
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	11/03/26
Vet - C10 a)	VNRA - Vet - C10 a) - - Vet - C10 a) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: administrative information concerning the holder's representative	04/09/25
Vet - F.II.f.1 a) 2.	VRA-R - Vet - F.II.f.1 a) 2. - a) Extension of the shelf life of the finished product 2. After first opening (supported by real time data) - F.II.f.1 a) 2. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data)	23/06/25
Vet - F.II.e.5 b)	VRA-S - Vet - F.II.e.5 b) - b) Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products. - F.II.e.5 b) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products.	23/06/25
Vet - F.II.a.3 b) 1.	VRA-S - Vet - F.II.a.3 b) 1. - b) Other excipients 1. 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 - F.II.a.3 b) 1. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - 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	23/06/25

	medicinal product	
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	05/10/23
Vet - A1 e)	VNRA - Vet - A1 e) - e) Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	25/09/23
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 placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	08/06/23