VPA10989/053/001

Domidine 10 mg/ml solution for injection, for horses and cattle

Variation	Summary	Date
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	14/04/25
Vet - G.I.2 b)	VRA-S - Vet - G.I.2 b) - b) Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product - G.I.2 b) Safety, Efficacy, Pharmacovigilance changes - 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	14/04/25
B.I.b.1.c	IA - B.I.b.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method	02/03/22
B.I.b.1.b	IA - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits	02/03/22
B.I.b.1.b	IA - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits	02/03/22
B.I.b.1.b	IA - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b -	02/03/22

	QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits	
B.I.a.2.e	IB - B.I.a.2.e - e) Minor change to the restricted part of an Active Substance Master File - B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	02/03/22
B.II.b.4.a	IB - B.II.b.4.a - a) Up to 10-fold compared to the originally approved batch size - B.II.b.4.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	28/02/22