

VPA10664/004/001

Domosedan 10 mg/ml solution for injection

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	07/07/26
Vet - B12 a)	VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient	17/06/26
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	17/06/26
Vet - C10 b)	VNRA - Vet - C10 b) - - Vet - C10 b) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: other changes	17/12/25
Vet - C9	VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	17/10/25
Vet - F.V.b 1. b)	VRA-S - Vet - F.V.b 1. b) - b) Harmonisation of the quality dossier after a SPC harmonisation procedure - F.V.b 1. b) Quality Changes - Changes to a marketing authorisation resulting from other regulatory procedures - Harmonisation of the quality dossier - Harmonisation of the quality dossier after a SPC harmonisation procedure	22/05/24
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	08/08/23
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier -	14/04/23

	F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	
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