VPA23462/016/001

Dexrapid 2 mg/ml solution for injection

Variation	Summary	Date
Vet - B11 c)	VNRA - Vet - B11 c) - - Vet - B11 c) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: tightening of specification limits of the immediate packaging of the active substance	29/04/26
Vet - B11 c)	VNRA - Vet - B11 c) - - Vet - B11 c) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: tightening of specification limits of the immediate packaging of the active substance	29/04/26
Vet - B3 g)	VNRA - Vet - B3 g) - - Vet - B3 g) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	29/04/26
Vet - B3 g)	VNRA - Vet - B3 g) - - Vet - B3 g) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	29/04/26
Vet - B3 g)	VNRA - Vet - B3 g) - - Vet - B3 g) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	29/04/26
Vet - B3 g)	VNRA - Vet - B3 g) - - Vet - B3 g) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	29/04/26
Vet - B11 e)	VNRA - Vet - B11 e) - - Vet - B11 e) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: addition of a new specification parameter to the specification with its corresponding test method for the immediate packaging of the active substance	29/04/26
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - - Vet - F.I.a.2 d) - Changes in the manufacturing process of the active substance - Minor change	16/04/26

	to the restricted part of an Active Substance Master File	
Vet - F.II.f.1 a) 1.	VRA-R - Vet - F.II.f.1 a) 1. - - Vet - F.II.f.1 a) 1. - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	27/11/25
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	07/08/25
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)	07/04/25
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	06/06/23
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)	06/06/23