VPA10996/021/001

Chorulon 1500 IU Powder and solvent for solution for injection

Variation	Summary	Date
Vet - F.II.b.2 a) 1.	VRA-S - Vet - F.II.b.2 a) 1. - - Vet - F.II.b.2 a) 1. - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed at the site is a biological/immunological method	11/08/26
Vet - F.I.a.1 g)	VRA-S - Vet - F.I.a.1 g) - - Vet- F.I.a.1 g)- Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place	11/08/26
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	16/07/26
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	16/07/26
Vet - F.I.b.1 b)	VRA-S - Vet - F.I.b.1 b) - - Vet - F.I.b.1 b) - 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 - Change outside the approved specifications limits range for the active substance	16/07/26
Vet - F.I.b.1 z)	VRA-R - Vet - F.I.b.1 z) - - Vet - F.I.b.1 z) - 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	16/07/26
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	17/02/26
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	30/07/25

	accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	17/01/24
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 - 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	21/03/23
Vet - F.II.e.1 a) 2.	VRA-S - Vet - F.II.e.1 a) 2. - a) Qualitative and quantitative composition 2. Sterile medicinal products and biological/immunological medicinal products. - F.II.e.1 a) 2. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products.	09/01/23