VPA10996/086/001

Nobilis Rismavac + CA126

Variation	Summary	Date
B.II.f.1.b.1	IB - B.II.f.1.b.1 - 1. As packaged for sale (supported by real time data) - B.II.f.1.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Stability - 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)	29/07/22
B.II.f.1.d	IB - B.II.f.1.d - d) Change in storage conditions of the finished product or the diluted/reconstituted product - B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product	29/07/22
A.7	IA - A.7 - A.7 Deletion of manufacturing sites 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, reagent or excipient (when mentioned in the dossier)* - A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites 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, reagent or excipient (when mentioned in the dossier)*	29/07/22
A.7	IA - A.7 - A.7 Deletion of manufacturing sites 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, reagent or excipient (when mentioned in the dossier)* - A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites 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, reagent or excipient (when mentioned in the dossier)*	29/07/22
B.II.a.6	IB - B.II.a.6 - B.II.a.6 Deletion of the solvent / diluent container from the pack - B.II.a.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Deletion of the solvent / diluent container from the pack	29/07/22
B.II.a.6	IB - B.II.a.6 - B.II.a.6 Deletion of the solvent / diluent container from the pack - B.II.a.6 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Deletion of the solvent / diluent container from the pack	29/07/22
B.II.e.5.a.2	IB - B.II.e.5.a.2 - 2. Change outside the range of the currently approved pack sizes - B.II.e.5.a.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the	29/07/22

	currently approved pack sizes	
B.II.e.5.a.1	IAin - B.II.e.5.a.1 - 1. Change within the range of the currently approved pack sizes - B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	29/07/22
B.II.a.3.b.3	II - B.II.a.3.b.3 - 3. Change that relates to a biological/immunological product - B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	29/07/22
B.I.a.1.e	II - B.I.a.1.e - e) The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - B.I.a.1.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - 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 - The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product	09/06/22