

VPA23216/001/001

Adequan 100 mg/ml Solution for Injection

Variation	Summary	Date
Vet – B24 b)	VNRA - Vet – B24 b) - B24 Replacement or addition of a manufacturer responsible for b) - B24 Replacement or addition of a manufacturer responsible for b)- batch release not including batch control or testing of a sterile or non-sterile finished product.	24/06/24
Vet - F.II.b.2 a) z.	VRA-S - Vet - F.II.b.2 a) z. - a) Replacement or addition of a site where batch control/testing takes place z. Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.2 a) z. Quality Changes - Finished Product -Manufacture - 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	18/12/23
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	18/12/23
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)	09/06/23
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.	06/01/23