VPA10836/001/001

Dalmazin 75 micrograms/ml solution for injection for cows and sows

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	07/10/26
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	07/10/26
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - - Vet - F.II.e.1 b) 2. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products	07/08/25
Vet - F.II.e.5 b)	VRA-S - Vet - F.II.e.5 b) - - Vet - F.II.e.5 b) - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products.	07/08/25
Vet - F.II.e.1 a) 2.	VRA-S - Vet - F.II.e.1 a) 2. - - Vet - F.II.e.1 a) 2. - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products.	07/08/25
Vet - I.I.1 a)	VRA-E - Vet - I.I.1 a) - - Vet - I.I.1 a) - 1 Changes to the active substance(s) - Replacement of a chemical active substance by a different salt/ester complex/derivative, with the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different	07/08/25
Vet - G.I.7 a)	VRA-E - Vet - G.I.7 a) - a) Addition of a new therapeutic indication or modification of an approved one - G.I.7 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/07/24
Vet - I.III.1	VRA-E - Vet - I.III.1 - a) Change or addition of target species - I.III.1 a) Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species - Other changes specific to veterinary medicinal products to be administered to food-producing animals - Change or addition of target species	22/07/24
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,	09/03/23

	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	