

VPA10996/282/001

CeptraShort 300 mg Intramammary Suspension for dairy cows at drying-off

Variation	Summary	Date
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - - Vet - F.I.a.1 a) - 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 - Introduction of a manufacturer of the active substance supported by an ASMF	25/08/26
Vet - A1 e)	VNRA - Vet - A1 e) - - Vet - A1 e) Administrative changes - Change in the name or address of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	27/05/26
Vet - A1 e)	VNRA - Vet - A1 e) - - Vet - A1 e) Administrative changes - Change in the name or address of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	16/04/26
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - - Vet - F.I.b.2 b) - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate	04/03/26
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 - 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, 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	14/08/24
Vet - B11 c)	VNRA - Vet - B11 c) - c) Tightening of specification limits of the immediate packaging of the active substance - B11 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material,	19/03/24

	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	
Vet - F.II.b.1 a)	VRA-S - Vet - F.II.b.1 a) - a) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological veterinary medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - F.II.b.1 a) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological veterinary medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes	18/12/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	06/07/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	25/05/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	21/02/23
A.2.b	IB - A.2.b - b) for Nationally Authorised Products - A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products	28/02/22