

VPA10996/282/001

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

Variation	Summary	Date
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, 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	19/03/24
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)	28/02/22

	name of the medicinal product - for Nationally Authorised Products	
--	--	--