VPA23174/003/001

DIB 1.0 g Vaginal Delivery System for Cattle

Variation	Summary	Date
Vet - B44 b)	VNRA - Vet - B44 b) - - Vet - B44 b) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient - New cerificate	19/08/26
Vet - B44 b)	VNRA - Vet - B44 b) - - Vet - B44 b) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient - New cerificate	19/08/26
Vet - B3 t)	VNRA - Vet - B3 t) - - Vet - B3 t) - Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance;— for a starting material, reagent or intermediate used in the manufacturing process of the active substance;— for an excipient	19/08/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	25/02/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	25/02/26
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	10/09/25
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	07/03/25
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administratvie changes: Change in the name or address or contact details of the marketing authorisation holder	29/01/25
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.	29/01/25
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	29/01/25
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the	19/12/24

	dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	11/12/24
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	20/11/24
Vet - C10 b)	VNRA - Vet - C10 b) - b) Other changes - C10 b) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — other changes	09/06/23