



To: Importers of Veterinary medicines Veterinary Pharmacies Veterinary drug shops Veterinary Clinics

Dear all,

SUBJECT: Recall of Veterinary medicines

The role of the Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the law N° 003/2018 of 09/02/2018 to health professionals and to other concerned organs. The Authority takes into considerations every serious information from Partners to ensure safe and quality products.

Reference made to the notification from Pharmaceutical Industry (Vetindia Pharmaceuticals Ltd), and Veterinary wholesaler (Global Organics Rwanda) that Envit of batch BN: EEV1807, EEV1808 and EEV1713 were found with problem of sedimentation. Therefore, we regret to notify you that the following batches have quality issues:

DESCRIPTION BATCH Exp. date	Composition	Manufacturer
Envit 100 ml BN: EEV1807 Exp. date: 07/2020		Manufacturer Vetindia Pharmaceuticals Limited A-6/1, Electronic complex, Kushaiguda, Hyderabad-500 062. Telangana (India)



			 D-panthenol USP 1 mg Vitamin B12 USP 10 mg D-biotin USP 10 mg Calcium glycerophosphate BP 10 mg Phenol (as preservative) USP 0.5% w/v 	
Envit 100 ml	EEV1808	07/2020	Each 100 ml contains - Vitamin A USP 2000 IU - Vitamin D3 USP 2000 IU - Vitamin E acetate: 4 mg - Niacinamide USP 10 mg - Thiamine hydrochloride USP 10 mg - Pyridoxine hydrochloride USP 10 mg - Riboflavin Phosphate sodium USP 5 mg - Sodium USP 1 mg - Departhenol USP 1 mg - Vitamin B12 USP 10 mg - Vitamin B12 USP 10 mg - Calcium glycerophosphate BP 10 mg - Phenol (as preservative) USP 0.5% w/v	Vetindia Pharmaceuticals Limited A-6/1, Electronic complex, Kushaiguda, Hyderabad-500 062. Telangana (India)
Envit 100 ml	EEV1713	10/2019	Each 100 ml contains: - Vitamin A USP 2000 IU - Vitamin D3 USP 2000 IU - Vitamin E acetate: 4 mg - Niacinamide USP 10 mg - Thiamine hydrochloride USP 10 mg - Pyridoxine hydrochloride USP 10 mg - Riboflavine Phosphate sodium USP 5 mg - Sodium USP 1 mg - D-panthenol USP 1 mg - Vitamin B12 USP 10 mg	Vetindia Pharmaceuticals Limited A-6/1, Electronic complex, Kushaiguda, Hyderabad-500 062. Telangana (India)

- D-biotin USP 10 mg - Calcium glycerophosphate BP 10 mg - Phenol (as preservative) USP 0.5% w/v
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Action to be taken

Rwanda Food and Drug Authority instructs all Veterinary Drugs Importers, Veterinary drug wholesalers, Veterinary Pharmacies, Veterinary drug shops and Veterinary clinics to immediately stop the distribution and dispensing of the above incriminated batches and return them to suppliers for suitable disposal management.

Sincerely,

Dr. Charles KARANGWA

Ag. Director General of Rwanda FDA

CC:

- Hon. Minister of Health
- Hon. Minister of Agriculture
- Director General of Rwanda Agriculture Board (RAB)