

Rwanda Food and Drugs Authority P.O. Box 84 Kigali

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Kigali on, 12/06/2020 Ref. Nº:DIS/ 1164 /RwandaFDA/2020

www.rwandafda.gov.rw Wholesalers of veterinary medicines (All) Importers of veterinary medicines (All)

Retailers of veterinary medicines (All) Veterinary doctors(All)

Title: Recall for batches of Benzylpenicillin procaine+Dihydrostreptomycin(DHS) (Prostrep20/20) injectable suspension

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority especially in its article 8 Paragraph 13, reference is also made to the inspection conducted by Rwanda FDA in veterinary pharmacies from 26th May 2020 to 05th June 2020. The following batches of veterinary medicine were found with sedimentation at the bottom of the bottles which is an indication of poor quality products.

Description	Batch/Lot	Mfg.date	Exp.date	Importer/Distribute	Manufacturer
D	MI12.06	01/2010	01/2021		DUCIUZINI
Benzylpenicillin	MI12-06	01/2019	01/2021	MOTLEY	PUSHKIN
Procaine 200mg +				HEALTHCARE	LABORATORY
Dihydrostreptomy		CAN		Ltd/KIGALI	LLC/RUSSIA
cin sulfate 200mg	MI12-07	01/2019	06/2022	MOTLEY	PUSHKIN
				HEALTHCARE	LABORATORY
Injection				Ltd/KIGALI	LLC/RUSSIA
suspension 100ml	MI12-08	01/2019	01/2021	MOTLEY	PUSHKIN
		1 AL 14		HEALTHCARE	LABORATORY
		ALC: N		Ltd/KIGALI	LLC/RUSSIA
	MI12-09	01/2019	01/2021	MOTLEY	PUSHKIN
				HEALTHCARE	LABORATORY
				Ltd/KIGALI	LLC/RUSSIA
	MI12-10	02/2019	02/2021	MOTLEY	PUSHKIN
	anoa	LOO0	1.9110	HEALTHCARE	LABORATORY
				Ltd/KIGALI	LLC/RUSSIA
	MI12-11	02/2019	02/2021	MOTLEY	PUSHKIN
				HEALTHCARE	LABORATORY
				Ltd/KIGALI	LLC/RUSSIA
	MI12-12	03/2019	03/2021	MOTLEY	PUSHKIN
				HEALTHCARE	LABORATORY
				Ltd/KIGALI	LLC/RUSSIA

#### Action to be taken

- Rwanda Food and Drug Authority instructs all importers, wholesalers, retailers of veterinary medicines and Veterinary doctors to stop their distribution, dispensing and use of the above incriminated batch of Benzylpenicillin procaine + Dihydrostreptomycin and return them to the suppliers for suitable disposal management.
- The importers and Suppliers of incriminated batch Benzylpenicillin+Dihydrostreptomycin are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock on hand.



#### <u>CC:</u>

- Hon. Minister of Agriculture and Animal Resources
- Director General of RAB

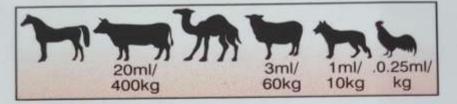
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### Benzylpenicillin Procaine + DHS

Withdrawal times: Slaughter : 28 days; for milk : 7days.



Further information see insert leaflet.

Licence N.Code : 161/UA/UK/SC/P-2007

Batch No. : MI12-07 Mfg. Date : 01/2019 Exp. Date : 01/2021

\* TRADE MARK



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