



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

Reference Number : **2024/006**

1. To: World Health Organisation, Market Authorisation Holders, Distributors, Retailers and Consumers	
2. Product Class of Defect: Class 1	3. Substandard
4. Product : EFINOX 1% w/v and 0.5% w/v	5. Marketing Authorisation Number : 21558 and 21553 For use in humans
6. Brand/Trade Name : EFINOX 1% w/v and 0.5% w/v	7. INN or Generic Name : Ephedrine Hydrochloride Nasal Drops
8. Dosage Form : Nasal Drops	9. Strength : 1% w/v and 0.5% w/v
10. Batch Numbers : 82979 and 82978	11. Expiry Date : 01/2025
12. Pack size and Presentation : 5ml plastic bottle	13. Date Manufactured : 02/2023
14. Marketing Authorisation Holder : Laboratory And Allied Ltd	
15. Manufacturer : Laboratory And Allied Ltd Contact Person : Dr. Mercy Okodoi Telephone : 0722 406189	16. Recalling Firm (if different) : N/A Contact Person : Dr. Mercy Okodoi Telephone : 0722 406189
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred : : Laboratory And Allied Ltd Contact Person : Dr. Mercy Okodoi Telephone : 0722 406189	

17. Recall Number Assigned (if available) : REC/2024/019
18. Details of Defect/Reason for Recall : Wrong product (label and contents are different products).
19. Information on distribution including exports (type of customer, e.g. hospitals) : consumer/patients
20. Action taken by Issuing Authority : Mandatory recall of EFINOX 1% w/v and 0.5% w/v (EPHEDRINE HYDROCHLORIDE NASAL DROPS) BATCH No. 82979, 82978.
21. Proposed Action : Healthcare Professionals to quarantine all the remaining stock and stop further distribution, sale, issuing, or use of the batches immediately. Await contact from Laboratory and Allied to arrange the return and Patients and members of the public who have the product batch are advised to immediately return the product to the nearest healthcare facility.

22. From (Issuing Authority): Kenya Pharmacy and Poisons Board	23. For Feedback Contact: pms@ppb.go.ke Telephone: 0795743049
24. Date : 22nd November 2024	