



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

Reference Number : **2024/005**

1. To: World Health Organisation, Market Authorisation Holders, Distributors, Retailers and Consumers	
2. Product Class of Defect: Class 1	3. Substandard
4. Product : Flamodip	5. Marketing Authorisation Number: 17699 For use in humans
6. Brand/Trade Name : Flamodip	7. INN or Generic Name: Amlodipine
8. Dosage Form : Tablets	9. Strength: 5mg
10. Batch number: FLD303	11. Expiry Date: 09/2026
12. Pack size and Presentation: 3*10s	13. Date Manufactured: 10/2023
14. Marketing Authorisation Holder: Harleys Limited	
15. Manufacturer: Medico Remedies Ltd, India Contact Person: Dr. Stephen Oduor Telephone: 0718184967	16. Recalling Firm (if different): Harleys Limited Contact Person: Dr. Stephen Oduor Telephone: 0718184967
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred: MEDICO REMEDIES LTD Contact Person: Dr. Stephen Oduor Telephone: 0718184967	
17. Recall Number Assigned (if available): REC/2024/025	

18. Details of Defect/Reason for Recall: Wrong product (label and contents are different products). The label of the secondary package for Flamodip (Amlodipine) 5 Mg Tablets reads Flamodip-5 (Amlodipine) whereas the primary package reads Flaminopril-5 (Enalapril).
19. Information on distribution including exports (type of customer, e.g. hospitals): consumer/patients
20. Action taken by Issuing Authority: Mandatory recall of flamodip (Amlodipine) 5 Mg Tablets Batch No FLD303 Manufactured By Medico Remedies Pvt Ltd.
21. Proposed Action: by healthcare Professional Quarantine all the remaining stock and stop further distribution, sale, issuing, or use of the batch immediately. Await contact from Harleys Limited 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: 26th September 2024	