



MINISTRY OF HEALTH  
PHARMACY AND POISONS BOARD

**RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL**

Reference Number : **2025/008**

1. To: **World Health Organisation, Market Authorisation Holders, Distributors, Retailers and Consumers**

2. Product Class of Defect: **Class I**

3. **Substandard**

4. Product : **S-Prazo**

5. Marketing Authorisation Number:  
**17699**

For use in humans

6. Brand/Trade Name : **S-Prazo**

7. INN or Generic Name: **Esomeprazole  
Magnesium Delayed-Release Capsules  
40mg**

8. Dosage Form : **Capsules**

9. Strength: **40mg**

10. Batch number: **SPZ 404**

11. Expiry Date: **08/2027**

12. Pack size and Presentation: **30's**

13. Date Manufactured: **09/2024**

14. Marketing Authorisation Holder: **Harleys Limited**

15. Manufacturer : **Medico Remedies  
Ltd, India**

16. Recalling Firm (if different): **Harleys  
Limited**

15. Where the defect is attributed to a  
manufacturing site, site where defect  
occurred: **Medico Remedies Ltd, India**

Contact Person: **Dr. Stephen Oduor**

Telephone: **+254 722 202030 | 0773 106  
788 | 0737 203030.**

17. Recall Number Assigned (if available): **REC/2025/017**

18. Details of Defect/Reason for Recall: **The product is being recalled following a market complaint of a product mix-up involving S-Prazo (Esomeprazole 40mg) Batch No. SPZ404, wherein it was detected and confirmed that a strip of Levofloxacin 500mg tablet was found in a pack of Esomeprazole 40mg Capsules.**

19. Information on distribution including exports (type of customer, e.g. hospitals):  
**consumer/patients**

20. Action taken by Issuing Authority: **Mandatory Recall of S-Prazo Batch Number SPZ 404**

21. Proposed Action: **Healthcare Professionals to 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](mailto:pms@ppb.go.ke)

Telephone:

**0795743049**

24. Date: **24<sup>th</sup> April 2025**