



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL

Reference Number : **2024/004**

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-302**

11. Expiry Date: **11/2026**

12. Pack size and Presentation: **3*10s**

13. Date Manufactured: **12/2023**

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**

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

Contact Person: **Dr. Stephen Oduor**

Telephone: **0718184967**

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17. Recall Number Assigned (if available): **REC/2024/021**

18. Details of Defect/Reason for Recall: **Market complaint wherein it was reported that there was a mixup with Donystatin Tablets blisters within some secondary packets “two different blister strips within one outer carton”.**

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

20. Action taken by Issuing Authority: **urgent voluntary recall of S-PRAZO (Esomeprazole Magnesium Delayed-Release Capsules 40mg) Batch No SPZ-302 Manufactured by Medico Remedies Pvt Ltd, India.**

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

Telephone: **0795743049**

24. Date: **15th August 2024**