

# Medicine Quality Alert: Class II Recall of Fluconazole 200mg Tablets manufactured by Universal Corporation Ltd

The Pharmacy and Poisons Board has initiated a mandatory recall of Fluconazole 200mg tablets (*a list of batches is enclosed in the table below*) manufactured by Universal Corporation Ltd due to white discoloration on pink tablets and dark stains on PVC and Unit boxes

From: Pharmacy and Poisons Board  
Published: 4<sup>th</sup> May 2023

**Recall Reference Number:** REC/2023/005

**Recall Classification:** Class II

**Recall Level:** Retail/Facility level

**Manufacturer:** Universal Corporation Ltd, Kenya

**Product name:** Fluconazole 200mg Tablets

**Active Pharmaceutical Ingredient:** Fluconazole

**Affected Counties:** All

## Affected Batches

	<b>Batch Number</b>	<b>Date Of Manufacture</b>	<b>Date Of Expiry</b>	<b>Pack Size</b>
1.	5811394	01.09.2022	31.08.2025	100 tablets
2.	5811393	01.09.2022	31.08.2025	100 tablets
3.	5811392	01.09.2022	31.08.2025	100 tablets
4.	5811391	01.09.2022	31.08.2025	100 tablets
5.	5811390	01.09.2022	31.08.2025	100 tablets
6.	5811185	27.07.2022	26.06.2025	100 tablets
7.	5811183	27.07.2022	26.06.2025	100 tablets
8.	5811184	27.07.2022	26.06.2025	100 tablets
9.	5811182	27.07.2022	26.06.2025	100 tablets
10.	5811125	09.07.2022	30.06.2025	100 tablets
11.	5811123	09.07.2022	30.06.2025	100 tablets
12.	5811124	09.07.2022	30.06.2025	100 tablets
13.	5811122	09.07.2022	30.06.2025	100 tablets
14.	5811121	09.07.2022	30.06.2025	100 tablets
15.	5811120	09.07.2022	30.06.2025	100 tablets
16.	5810962	07.06.2022	30.05.2025	100 tablets
17.	5810961	07.06.2022	30.05.2025	100 tablets
18.	5810959	07.06.2022	30.05.2025	100 tablets

19.	5810960	07.06.2022	30.05.2025	100 tablets
20.	5810958	07.06.2022	30.05.2025	100 tablets
21.	5810320	01.02.2022	31.01.2025	100 tablets
22.	5810319	01.02.2022	31.01.2025	100 tablets
23.	5810318	01.02.2022	31.01.2025	100 tablets
24.	5810317	01.02.2022	31.01.2025	100 tablets
25.	5810316	01.02.2022	31.01.2025	100 tablets
26.	5810315	01.02.2022	31.01.2025	100 tablets
27.	5810022	01.11.2021	31.10.2024	100 tablets
28.	5810021	01.11.2021	31.10.2024	100 tablets
29.	5809602	01.08.2021	31.07.2024	100 tablets

### **Brief description of the problem**

The Pharmacy and Poisons Board has mandated Universal Corporation Ltd to initiate an urgent recall of specific batches of Fluconazole 200mg, following several market complaints of white discoloration on pink tablets and dark stains on the Polyvinyl chloride (PVC) blisters and unit boxes.

### **Action for healthcare professionals**

You are advised to immediately quarantine all remaining stock and stop further distribution and sale of the impacted batches. Universal Corporation Ltd will contact you to arrange the return of the product.

### **Action for patients and caregivers**

No further action is required by patients as this is a Retail/hospital Pharmacy level recall. Patients should continue taking other batches of the product other than the impacted batches and as prescribed by the healthcare professional.

### **Further Information**

For stock inquiries please contact Universal Corporation Limited by email: [info@ucl.co.ke](mailto:info@ucl.co.ke) and [caroline.kimani@ucl.co.ke](mailto:caroline.kimani@ucl.co.ke) or via telephone on +254 722707126, +254 721922280, +254 734513075, +254 738279223, +254 738279224, +254(0) 202693836, +254(0) 202693835, +254(0) 202693834

You are encouraged to promptly report any cases of adverse reactions and suspected substandard or falsified products to the nearest healthcare facility or through the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>
- USSD code at \*271#
- Email [pv@ppb.go.ke](mailto:pv@ppb.go.ke) or [pms@ppb.go.ke](mailto:pms@ppb.go.ke)
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email: [pms@ppb.go.ke](mailto:pms@ppb.go.ke)