# Medicine Quality Alert: Class II Product Recall of Biodine Mouth Gargle by Biodeal Laboratories Limited

Biodeal Laboratories Limited is recalling six batches of Biodine Mouth Gargle due to discoloration of the product; the batches 0122081, 0122082, 0322054, 0322055, 0322056 & 0322057.

From: Pharmacy and Poisons Board Published: 12th September 2022

Recall Reference Number: REC/2022/08

Recall Classification: Class II Recall Level: Retail/Facility Level

Manufacturer: Biodeal Laboratories Limited, Kenya

**Product name:** Biodine Mouth Gargle

Active Pharmaceutical Ingredient: Povidone iodine 1% w/v

**Affected Batches** 

Batch number	Expiry date	Pack Size
0122081	12/2023	100ml
0122082	12/2023	100ml
0322054	12/2023	100ml
0322055	12/2023	100ml
0322056	12/2023	100ml
0322057	12/2023	100ml

# Brief description of the problem

The above six batches of Biodine Mouth Gargle had changed color to colorless.

## Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of batch batches *0122081*, *0122082*, *0322054*, *0322055*, *0322056* & *0322057* immediately and await contact from Biodeal Laboratories Limited team to arrange for the return of the products.

## **Action for patients**

Biodine Mouth Gargle is used as an antiseptic. Talk to your prescribing healthcare professional if you have the above batches of Biodine Mouth Gargle.

## **Further Information**

For any enquiries on consignments of the products, please contact Biodeal Laboratories Limited by email at <u>regulatoryaffairs@biodealkenya.com</u> or by phone at +254 720 333 829.

Promptly report any cases of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

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

For any further information please contact the Pharmacy and Poisons Board by email: <a href="mailto:pms@ppb.go.ke">pms@ppb.go.ke</a>