

Medicine Quality Alert: Class II Recall of DTO (Ornidazole/Ofloxacin) tablets, Batch Number DDBR2201

Two Kay Chemicals Limited is implementing an urgent voluntary recall of DTO (Ornidazole/Ofloxacin) Batch number DDBR2201 due to color change.

From: Pharmacy and Poisons Board
Published: 17th August 2023

Recall Reference Number: REC/2023/009

Recall Classification: Class II

Recall Level: Retail/Facility level

Local Technical Representative: Two Kay Chemicals

Manufacturer: Ms. Coral Laboratories Ltd, India

Product name: DTO Tablets

Active Pharmaceutical Ingredient: Ornidazole/Ofloxacin

Affected Counties: All

Affected batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
DDBR2201	05/2022	04/2025	10'S

Brief description of the problem

Two Kay Chemicals Limited has initiated an urgent recall of DTO (Ornidazole/Ofloxacin) due to market complaints regarding a quality defect in product batch number DDBR2201. The nature of the complaint is a color change.

The Pharmacy and Poisons Board conducted an investigation and concluded that the product was out of specification (OOS). Quality control analysis confirmed that the product failed to meet the specifications of description.

Action for healthcare professionals

You are advised to stop supplying the above batches and immediately quarantine all the remaining stock of the product. Two Kay Chemicals Limited will contact you to arrange the return of the impacted batches.

Action for patients and carers

Patients currently prescribed the impacted batches of DTO (Ornidazole/Ofloxacin) should seek advice from healthcare providers. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options.

Further Information

For stock enquiries please contact Two Kay Chemicals Limited at: twokay@bidii.com

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 pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the Pharmacy and Poisons Board by email: pms@ppb.go.ke