

Medicine Quality Alert: Class II Recall of Umbicare Gel manufactured by Indoco Remedies Ltd

Sai Pharmaceuticals(Kenya)Ltd is implementing a voluntary recall of Umbicare Gel Batch number **UA1M11C1B** due to out-of-specification analysis results on related substances test.

From: Pharmacy and Poisons Board
Published: 13/12/2022

Recall Reference Number: REC/2022/10

Recall Classification: Class II

Recall Level: Retail/Facility level

Manufacturer: Indoco Remedies Limited, India

Local Technical Representative: Sai Pharmaceuticals(Kenya)Ltd

Product name: Umbicare Gel

Active Pharmaceutical Ingredient: Chlorhexidine Gluconate 7.1%w/w

Affected Batch

Batch number	Expiry date	Pack size
UA1M11C1B	08/2023	5g

Brief description of the problem

One batch of Umbicare Gel; **UA1M11C1B** had out-of-specification analysis results on related substances test.

Action for healthcare professionals

You are advised to immediately quarantine and stop supplying the remaining stocks of the impacted batches of the product. Sai pharmaceuticals will contact you to arrange for the return of the product.

Action for patients and carers

This recall is at the retail and wholesaler level and not directed to the patient level. Umbicare Gel is used as an antiseptic for the management of umbilical cord wounds in infants. Carers for patients who have been prescribed the impacted batches are advised to seek medical advice from their healthcare providers.

Further Information

For stock enquiries, please contact Sai Pharmaceuticals (Kenya) Ltd by email at head-regulatory@saipharm.com or by phone at +254 731 952 330.

You are advised to 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