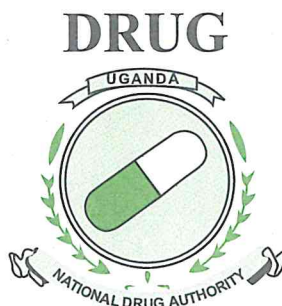


NATIONAL



AUTHORITY

Safe Drugs Save Lives

RAPID ALERT: CLASS 1 RECALL OF SUBSTANDARD VISIPAQUE (IODIXANOL)

Date: 17th June, 2026

Alert Reference Number: 01/2026

Issued by: National Drug Authority

The Authority informs the **health care professionals, hospitals, clinics, distributors, and patients.**

Product name: VISIPAQUE (Iodixanol).

Dosage form/device type/model: injectable solution.

Indication: Contrast medium used in X-ray and computed tomography (CT) imaging.

Strength: 320mg

Batch/Lot number: 17314000

Expiry date: 25th July, 2028

Manufacturer: GE Healthcare Ireland Limited.

Marketing authorization holder/importer/distributor: Phillips Pharmaceutical (U) Ltd.

Reason for alert:

The World Health Organization notified the National Drug Authority of a substandard VISIPAQUE product following the detection of metallic particulate matter adhered to or embedded within the inner surface of the polypropylene bottles. Since VISIPAQUE is administered by intravenous and intra-arterial routes, the presence of visible solid particles represents a serious patient safety risk. Accidental administration of particulate matter may obstruct small blood vessels and result in severe or life-threatening embolic complications, including pulmonary embolism, stroke, myocardial ischemia, respiratory distress, and possible multi-organ failure.

Healthcare facilities are at increased risk where strict visual inspection of the product is not performed before administration.

Advice to health care professionals and facilities:

1. Phillips Pharmaceutical Ltd to recall the products on the market for destruction.
2. Healthcare professionals must immediately isolate and halt the use of the affected batch and return stock to suppliers.
3. Health care professionals are urged to remain highly vigilant for adverse events related to particulate embolism.
4. Health care professionals are advised to inspect the products before use for any particulate matter.

HEAD OFFICE

Plot 93 Buganda Rd. P.O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100, Toll Free: 0800 101 999
☎ 0740 002 080 (General), 0740 002 070 (Pharmacovigilance)
Website: www.nda.or.ug, Email: ndaug@nda.or.ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority
NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: (+256) 417 782 040 / (+256) 414 583 095

OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

REGIONAL OFFICES

Central Region, Akamwesi - Tel: (+256) 414 672 734
Western Nile Region, Arua - Tel: (+256) 414 671 033
South Western Region, Mbarara - Tel: (+256) 414 671 034
South Eastern Region, Jinja - Tel: (+256) 434 122 176
Eastern Region, Tororo - Tel: (+256) 392 004308
Western Region, Hoima - Tel: (+256) 393 255 257
Northern Region, Lira - Tel: (+256) 414 671 032
Kampala Extra Region - Tel: (+256) 417 788 100

CONTINUATION SHEET

5. If a patient has suffered an adverse event or unexpected side effect following the administration of VISIPAQUE, please seek immediate medical intervention and report the clinical event to the nearest health facility or NDA without delay.

Contact for reports and inquiries:

Email: pms.nda.or.ug/druginfo@nda.or.ug

Whatsapp: 0740002070

Toll free: 0800101999

<https://primaryreporting.who-umc.org/UG>



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