Batch Recall

Product name	Authorisation no.	Batch no.	Expiry date
Omnipaque 350 mg I/ml Solution for Injection	PA 0735/006/020	17413362	15.10.2028
Visipaque 320 mg I/ml Solution for Injection	PA 0735/009/013	17230467	14.08.2028

20/03/2026

Dear Pharmacist,

We wish to advise you that the above batches of Omnipaque 350 mg I/ml Solution for Injection and Visipaque 320 mg I/ml Solution for Injection are being recalled with immediate effect.

This recall action is to **user level** and has been agreed with the Health Products Regulatory Authority (HPRA).

The recall is due to the potential presence of particles in 100ml polypropylene bottles in certain batches of the products. Glass bottle presentations are not affected by this defect.

Please perform the following actions:

1. Immediately identify and quarantine any packs from the above-listed batches within your facility. This includes stock at all locations within your pharmacy or facility, including at ward level or clinics.
2. Please complete and return the attached acknowledgement form by emailing it to Recall.89013@gehealthcare.com. GE Healthcare will arrange for product return and credit will be issued for stock returned by 6th April 2026.
3. Please make all relevant health care professionals aware of the contents of this recall letter.
4. If you have supplied units from the above listed batches to any other hospital, healthcare facility or user, please notify them of this recall action and forward them a copy of this recall letter.

Unimpacted stock is available to order at this time.

If you have any questions regarding this notification, please contact GE Healthcare at 00 1 800-292-8514. Adverse events should be reported to GE Healthcare at UKpharmacovigilance@gehealthcare.com and to the HPRA (medsafety@hpra.ie).

We apologise for any inconvenience this action may cause.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Safety Officer
GE HealthCare

GE HealthCare Ref. # 89013

RECALL ACKNOWLEDGEMENT FORM

RESPONSE REQUIRED

Please complete this form and return it to GE HealthCare promptly.

Facility Name: _____

Street Address: _____

City, Country and Eircode: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the product recall notification and have taken the appropriate actions in accordance with that notification.

Below is the list of impacted batches at our facility which we will be returning to GE HealthCare:

Batch number	Number of bottles

Please provide the name of the responsible individual who completed this form:

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

To complete this form via email, scan or take a photo of the completed form and email it to: Recall.89013@gehealthcare.com.