

Urgent Field Safety Notice – Product Recall

Omega Pregnancy Test Cassette
Product Code 001L040-50
Batch Numbers Affected
001L040-210330
001L040-50-210706
001L040-50-210810

06 May 2022,

Dear Customer,

Uniphar have being advised of a recall for Omega Pregnancy Test Cassette, please see affected lots in the table above.

The product manufacturer has advised that they have received reports of false positive test results for the Omega Pregnancy Test Cassette. The manufacturer has advised in order to prevent further false positive test results the decision has been made to recall the product for the affected lots in the table above.

Our records indicate that you may have received 1 or more of the products/batches listed above.

Could we please ask that you take the following actions for the product batches listed in the table above.

- Remove from sale any units of the affected batches on your premises and return to Uniphar by May 28th, 2022.
- Can you please contact all customers this product was sold to and request they return all unused product to your pharmacy.
- Please ensure this notice is circulated to all personnel who need to be informed of the recall in your organisation and to all personnel who need to be informed of the recall in any other organisation to which the affected devices may have been supplied.
- Put the recalled stock in a tote with a copy of this recall letter and include your account number.

Keep the stock isolated from any other returns and clearly mark the tote as 'Recalled Stock'.

Any returns received after May 28th will not be accepted for credit.

We apologise for any inconvenience this may cause. Should you have any queries, please contact Pharmasource by telephone on 1800 440 440 or by email at psquality@uniphar.ie.

Uniphar Group
Head Office
4045 Kingswood Road
Citywest Business Park
Co. Dublin
Tel: 01 428 7777
Fax: 01 428 7776
Email: dublin@uniphar.ie

Other Dublin Locations
Pharmapark
Chapelizod
Dublin 20
Tel: 01 630 5555
Fax: 01 630 5130
Email: dublin@uniphar.ie

Unit 645
Jordanstown Drive
Greenogue Business Park
Rathcoole
Co Dublin
Tel: 01 468 8250
Email: dublin@uniphar.ie

Limerick Office
Garryglass
Ballysimon Road
Limerick
Tel: 061 419 955
Fax: 061 419 300
Email: limerick@uniphar.ie

Sligo Office
5/7 Cleveragh
Business Park
Sligo
Tel: 071 919 3700
Fax: 071 916 1977
Email: sligo@uniphar.ie

Cork Office
South Cork Industrial Estate
Pouladuff Road
Cork
Tel: 021 496 5588
Fax: 021 496 5669
Email: cork@uniphar.ie

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Yours Sincerely,

DocuSigned by:

Sarah Lindsay

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Sarah Lindsay, Head of Supply Chain Quality / RP

06 May 2022

Uniphar Group

Head Office

4045 Kingswood Road
Citywest Business Park
Co. Dublin
Tel: 01 428 7777
Fax: 01 428 7776
Email: dublin@uniphar.ie

Other Dublin Locations

Pharmapark
Chapelizod
Dublin 20
Tel: 01 630 5555
Fax: 01 630 5130
Email: dublin@uniphar.ie

Unit 645
Jordanstown Drive
Greenogue Business Park
Rathcoole
Co Dublin
Tel: 01 468 8250
Email: dublin@uniphar.ie

Limerick Office

Garryglass
Ballysimon Road
Limerick
Tel: 061 419 955
Fax: 061 419 300
Email: limerick@uniphar.ie

Sligo Office

5/7 Cleveragh
Business Park
Sligo
Tel: 071 919 3700
Fax: 071 916 1977
Email: sligo@uniphar.ie

Cork Office

South Cork Industrial Estate
Pouladuff Road
Cork
Tel: 021 496 5588
Fax: 021 496 5669
Email: cork@uniphar.ie