



**PHARMACEUTICAL
COSMETICS AND
OVER THE COUNTER PRODUCTS**

Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co. Meath
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28th February 2017

URGENT FIELD SAFETY NOTICE: RECALL

Product Name: Freestyle Lite Test Strips

Type of Action: Recall

Dear Customer

It has come to our attention that there have been packs of Freestyle Lite Test Strips distributed by PCO which do not contain English language details on the outer carton. English language instructions are present on the bottle and on the Information Leaflet contained within the packs.

The following batches of Freestyle Lite Test Strips may be affected:

BATCH NO.	EXPIRY DATE
1527418	10/2017
1604815	03/2018
1605407	03/2018
1606712	03/2018
1606902	03/2018
1606904	03/2018
1606914	03/2018
1609207	04/2018
1609719	04/2018
1611909	05/2018
1613120	05/2018
1615113	06/2018
1615205	06/2018
1616801	07/2018
1617306	07/2018
1617306	07/2018
1619402	08/2018
1620203	08/2018
1621610	08/2018
1623511	09/2018
1624307	09/2018
1624420	09/2018
1625012	09/2018
1625811	09/2018
1625905	09/2018

1626513	10/2018
1627704	10/2018
1630701	11/2018

Action to be taken by pharmacists:

- Identify if you have devices from the affected batches.
- Identify whether there is English language contained on the outer carton.
- If you have packs which do not contain English language on the outer carton, please contact the Customer Service team at PCO Manufacturing before Fri 10th March to arrange for uplift of the affected stock.

If you have any further questions regarding the contents of this Field Safety Notice, please contact Niamh Clarke at 01-8356700.

PCO Manufacturing can confirm that this notice has been notified to the Health Products Regulatory Authority (HPRA).

We sincerely apologise for any inconvenience that this situation may have caused.

Sincerely,



Niamh Clarke, BSc(Pharm), MPSI
Regulatory Affairs Manager / Deputy Qualified Person
PCO Manufacturing