



FreeStyle Lite® Test Strips

IMB Safety Notice: SN2013(14)

Circulation Date: 04 December 2013

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NOTICE

MANUFACTURER/SUPPLIER

Abbott Diabetes Care

TARGET GROUPS

All Hospital staff
All Nursing Home staff
Risk Managers
Nursing Managers
Hospital Pharmacists
Diabetic Clinics/ outpatients
Diabetic nurse specialists
Diabetic departments
Endocrinology units
Endocrinology Consultants
Paediatric wards
Laboratory Managers
Chief Medical Scientists
Purchasing / Procurement / Material Managers
Pharmacists supplying these devices
General Practitioners
Healthcare professionals who use these devices
Healthcare professionals managing patients who use these devices
Carers
General public

ISSUE

The Irish Medicines Board (IMB) has been notified that certain lots (lot numbers 1284962 and 1372611) of FreeStyle Lite® Blood Glucose Test Strips may give erroneously low blood glucose results and may produce out of range control solution results when using FreeStyle® Blood Glucose Meters, FreeStyle Mini® Blood Glucose Meters and the FreeStyle® meter built into the Omnipod® System.

BACKGROUND

Abbott Diabetes Care (UK) has advised that blood glucose test strips from the affected lot numbers 1284962 (expiry date 2014-06) and 1372611 (expiry date 2015-02) were supplied to the Irish market.

This issue only affects lot numbers 1284962 and 1372611 when using FreeStyle® Blood Glucose Meters, FreeStyle Mini® Blood Glucose Meters and the FreeStyle® meter built into the Omnipod® System.

S A F E T Y NOTICE

Lot 1284962 was first placed on the Irish market on 04th February 2013 and lot 1372611 on 24th October 2013. Abbott Diabetes Care (UK) has confirmed that the above lot numbers are the only affected lots supplied to the Irish market and no adverse incidents related to this issue have been reported for the Irish market.

ACTION OR RECOMMENDATIONS

Advice for End Users / Patients:

1. Identify any test strips from the affected lots.
2. Follow the manufacturer's instructions outlined in the attached field safety notices (FSNs).
3. Discontinue use and dispose of test strips from the affected lots and contact Abbott Diabetes Care Customer Service on 008000 2255 232 or 1800 776633 for a replacement of the affected test strips.
4. Ensure that you can continue to appropriately monitor your blood glucose via test strips from a different lot number or by other means. This should be done in consultation with your healthcare professional.
 - Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).
 - Symptoms of high blood sugar may include: Excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

Advice for Healthcare Professionals / Pharmacists / Distributors:

1. Identify any test strips from the affected lots.
2. Follow the manufacturer's instructions outlined in the attached field safety notices (FSNs).
3. Discontinue use and dispose of test strips from the affected lots and contact Abbott Diabetes Care Customer Service on 1800 776633 for a replacement of the affected test strips.
4. Ensure that the appropriate personnel are made aware of this notice and the attached field safety notices. Please also pass this notice and the attached FSNs on to any end user or organisation where the potentially affected test strips have been transferred.
5. Ensure that end users who dispose of blood glucose test strips from the affected lots can continue to appropriately monitor their blood glucose.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Barbara Scott
Abbott Diabetes Care
4051 Kingswood Drive

S A F E T Y

NOTICE

Citywest Business Campus
Dublin 24

Telephone: 1800 776633
E-mail: ADChelpuk@abbott.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie