IRISH MEDICINES BOARD
SAFETY NOTICE

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GlucoMen LX Sensor blood glucose test strips 50 count (product code 38877), used with the GlucoMen LX and GlucoMen LX PLUS meter

IMB Safety Notice: SN2013(09)
Circulation Date: 20 August 2013

MANUFACTURER/SUPPLIER
A. Menarini Diagnostics S.r.l. (Italy)

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 of GlucoMen LX Sensor blood glucose test strips have been subject to a manufacturing fault and may give erroneously high blood glucose results, potentially leading to inappropriate insulin administration.

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BACKGROUND

A. Menarini Diagnostics (UK) and the distributor Medicon Ireland have advised that blood glucose test strips from affected lot number 3212214249 (expiry date 2014-08-31) were supplied to the Irish market. Based on stock distribution patterns, both A. Menarini Diagnostics (UK) and Medicon Ireland believe that is unlikely that strips from this lot remain in circulation. Furthermore, A. Menarini Diagnostics has indicated that only a limited number of strips from the lot are affected by this issue.

A. Menarini Diagnostics (UK) and Medicon Ireland have confirmed that the above lot number is the only affected lot which they supplied to the Irish market; other affected lots (3212145249, 3212278249, 3212219249 and 3212251249) have been distributed in other European countries.

ACTION OR RECOMMENDATIONS

Advice for End Users / Patients:

1. Identify, discontinue use and quarantine devices from the affected lot.
2. Return any devices from the affected lot to your pharmacy or distributor. Alternatively, contact A. Menarini Diagnostics (UK) or Medicon Ireland to arrange for return of any devices from the affected lot.
3. 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.

Advice for Healthcare Professionals / Pharmacists / Distributors:

1. Identify, discontinue distribution and quarantine devices from the affected lot.
2. Return any devices from the affected lot to your distributor. Alternatively, contact A. Menarini Diagnostics (UK) or Medicon Ireland to arrange for return of any devices from the affected lot.
3. Please also pass this notice on to any end user or organisation where the potentially affected devices have been transferred or who are using the GlucoMen LX and GlucoMen LX PLUS meters.
4. Ensure that the appropriate personnel and end users are made aware of this notice.
5. Ensure that end users who return blood glucose test strips from the affected lots can continue to appropriately monitor their blood glucose.

ENQUIRIES

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

SAFETY NOTICE

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

Enquiries to the distributor should be addressed to:

Mr. Jim McGrory
Medicon Ireland Ltd.
1a/1b Meridian Estate
Carnbane Business Park
Newry
Co. Down
BT356QH
Northern Ireland

Telephone: +44 2830 835 500
Fax: + 44 2830 835 544
E-mail: jimmcg@mediconire.com

Enquiries to the manufacturer should be addressed (via their UK affiliate) to:

Mr. Tony Jones
A. Menarini Diagnostics Ltd. (UK)
405 Wharfedale Road
Winnersh-Wokingham
RG41 5RA
Berkshire
United Kingdom

Telephone: +44 1189 444 100 or (+44 800 243 667)
Fax: +44 1189 444 123
E-mail: tony.jones@menarinidiag.co.uk