

Safety Notice

Medical Devices

NovoPen Echo[®] and NovoPen[®] 5 Insulin Pens

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2017(24)

Issue Date: 05th July 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Novo Nordisk	V32407

ISSUE

The HPRA has been informed of a market action affecting certain batches of NovoPen Echo[®] and NovoPen[®] 5 insulin pens. The action involves a recall of devices from the affected batches to pharmacy level and at patient level a replacement cartridge holder is being provided.

The action was initiated by the manufacturer after it was identified that the insulin cartridge holder used in specific batches of NovoPen Echo[®] and NovoPen[®] 5 insulin pens may crack or break if exposed to certain chemicals such as cleaning agents containing chlorine, iodine or alcohol.

Details of the action and the batches affected are described in the accompanying field safety notices (FSNs) circulated by Novo Nordisk.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSNs and follow the instructions provided by the manufacturer.
2. Do not stop treatment without consulting your healthcare professional.
3. Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSNs and follow the instructions provided.
2. Forward a copy of this Safety Notice and the FSNs, to all relevant personnel within your organisation, and to any organisation / persons where these devices have been transferred.

3. If you are in possession of devices within the scope of this action, please immediately quarantine and contact Novo Nordisk to order replacement stock and arrange for the return of affected stock.
4. Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS	
Ambulance services Carers Community care managers Community nurses Community therapists Diabetes clinics Diabetes nurse specialists Endocrinologists Endocrinology units General practitioners General public	Hospital managers / CEOs Medical directors Nursing homes Outpatient clinics Paediatricians Pharmacists Practice nurses Private medical practitioners Risk managers School nurses Supplies managers

BACKGROUND
<p>Novo Nordisk has concluded that the risk of cracking described above is due to the fact that plastic materials used for the insulin cartridge holders in the affected batches can be weakened if exposed to certain chemicals.</p> <p>The manufacturer has advised that using a device with a cracked/broken cartridge holder can result in the device delivering a smaller than intended insulin dose leading to an increase in blood sugar levels and a potential risk of hyperglycaemia.</p> <p>Replacement cartridge holders which are not affected by this issue can be requested free of charge from the manufacturer.</p> <p>Please refer to the accompanying FSNs for further details of this action and how to request a replacement holder.</p> <p>The HPRA is issuing this safety notice to raise awareness of this issue.</p>

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION		
<p>Enquiries to the manufacturer should be addressed to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Novo Nordisk Ltd. First Floor, Block A The Crescent Building Northwood Business Park Santry Dublin 9 </td> <td style="width: 50%; vertical-align: top;"> Telephone: 1850 665 665 Fax: +353 1 862 9725 E-mail: info@novonordisk.ie </td> </tr> </table>	Novo Nordisk Ltd. First Floor, Block A The Crescent Building Northwood Business Park Santry Dublin 9	Telephone: 1850 665 665 Fax: +353 1 862 9725 E-mail: info@novonordisk.ie
Novo Nordisk Ltd. First Floor, Block A The Crescent Building Northwood Business Park Santry Dublin 9	Telephone: 1850 665 665 Fax: +353 1 862 9725 E-mail: info@novonordisk.ie	

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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