

press release

Important safety information for people with diabetes using NovoPen Echo® and/or NovoPen® 5

Dublin, Ireland, 05 Jul 2017 – Novo Nordisk A/S has detected that the insulin cartridge holder used in a small number of NovoPen Echo® and NovoPen® 5 LOT/batch numbers may crack or break if exposed to certain chemicals, for example certain cleaning agents. NovoPen Echo® and NovoPen® 5 are used for insulin treatment by people with diabetes.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected LOT/batch numbers to contact Novo Nordisk in order to replace the cartridge holder as some could be damaged or subject to damage in the future if not changed. The affected LOT/batch numbers are listed below.

A picture of the cartridge holder is shown below



Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller dose of insulin than expected leading to high blood sugar levels. The risk of experiencing high blood sugar levels with the use of a device with an affected cartridge holder is evaluated to be less than 0.1%, i.e. less than 1 in 1000 patients will experience high blood sugar levels due to an affected cartridge holder.

The warning symptoms of high blood sugar levels (hyperglycaemia) normally appear gradually and can be flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea or vomiting). You might not experience any physical signs of high blood sugar, but only notice this in your blood sugar measurements.

Details of affected devices

The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in the below. Please note the batch number can differ on the pen from the box that it comes in.

NovoPen Echo®		NovoPen® 5	
LOT/batch number on carton	LOT/batch number on device	LOT/batch number on carton	LOT/batch number on device
DUG0191	DUG0191	EVG0902-2	EVG0902
DUG0192	DUG0192	EVG2293-1	EVG2293
DUG0193	DUG0193	EVG2910-2	EVG2910
DUG1613	DUG1613	EVG3008-1	EVG3008
DUG1614	DUG1614	EVG6245-1	EVG6245
DUG1615	DUG1615	FVG7150-1	FVG7150
DUG1616	DUG1616	FVG7565-2	FVG7565
DUG1708	DUG1708	FVG7566-2	FVG7566
DUG1709	DUG1709	FVG7612-1	FVG7612
DUG1775	DUG1775	FVG7613-1	FVG7613
DUG1776	DUG1776	FVG7613-2	FVG7613
DUG1778	DUG1778	FVG7616-1	FVG7616
DUG2049	DUG2049	FVG7617-2	FVG7617
DUG2053	DUG2053	FVG8531-2	FVG8531
DUG2129-1	DUG2129	FVG8532-1	FVG8532
EVG2298-6	EVG2298	FVG8654-2	FVG8654
EVG2300-2	EVG2300	FVG8657-2	FVG8657
EVG2909-1	EVG2909		
EVG3999-2	EVG3999		
EVG5963-3	EVG5963		
EVG6823-2	EVG6823		
FVG7337-5	FVG7337		
FVG7364-1	FVG7364		
FVG7457-1	FVG7457		
FVG8212-3	FVG8212		
FVG8217-1	FVG8217		
FVG8218-1	FVG8218		
FVG8995-1	FVG8995		
FVG8997-4	FVG8997		

Where to find the LOT/batch number for your NovoPen Echo® and NovoPen® 5

1. LOT/batch numbers of unopened NovoPen Echo® and NovoPen® 5 devices are printed on the back of the outer packaging/carton (Figure 1).

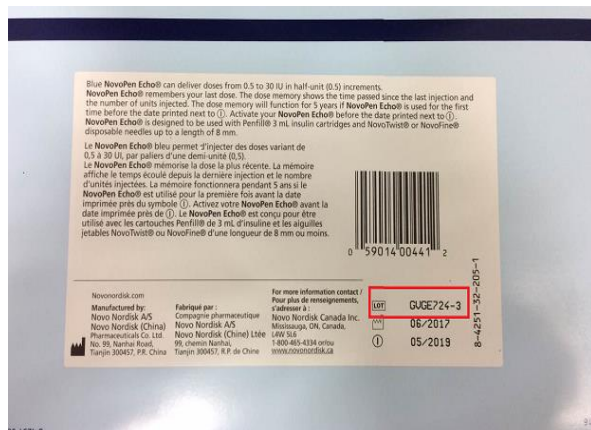


Figure 1. Red square shows where the LOT/batch number is located on a NovoPen Echo[®] and NovoPen[®] 5 e.g. the LOT/batch number on the above device is GVGE724-3

For NovoPen Echo[®] and NovoPen[®] 5 devices separated from their outer packaging/carton, the LOT/batch numbers are printed on NovoPen Echo[®] and NovoPen[®] 5 as indicated in Figure 2.

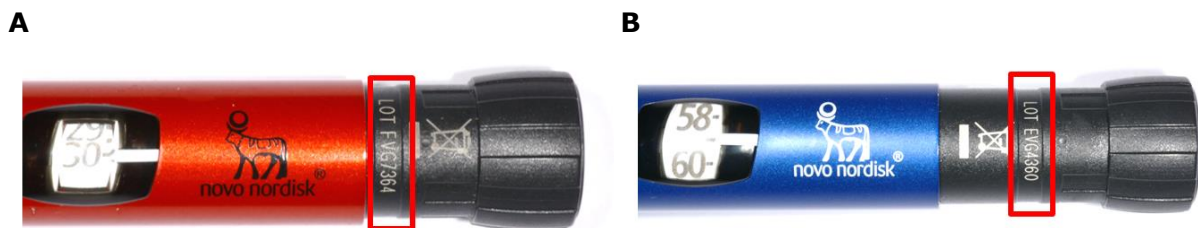


Figure 2. Red squares show where the LOT/batch number is located on A) NovoPen Echo[®] and B) NovoPen[®] 5. e.g. the LOT/batch number on the NovoPen Echo[®] to the left is FVG7364.

If patients are in possession of a NovoPen Echo[®] and/or a NovoPen[®] 5 device with a LOT/batch number which is **not** mentioned above, there is no reason for concern and you can be confident that the pen will work as intended.

Advice for patients using a NovoPen Echo[®] and/or NovoPen[®] 5 with one of the affected LOT/batch numbers:

- Do **not** stop treatment without consulting your healthcare professional.
- Be attentive to your blood sugar levels by checking them regularly and looking for symptoms of hyperglycaemia. If you note these symptoms, measure your blood sugar levels as instructed by your healthcare professional and take appropriate action.
- In the event that you experience symptoms of high blood sugar levels involving this product, contact your healthcare professional for advice.
- To request a replacement cartridge holder, register your contact details (name, address, phone number, email and number of affected cartridge holders) at www.novonordisk.com or contact Novo Nordisk on 1850 665 665.

- Upon receipt, you should attach the new cartridge holder and use as stated in the Instructions For Use.
- Report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

Novo Nordisk is committed to delivering high-quality products and sincerely apologises for this unfortunate situation and the concerns and inconvenience it may cause patients and healthcare professionals. We are working closely with Health Products Regulatory Authority to ensure patient safety and minimise the disruption this situation causes.

If you have any questions or concerns, please advise patients to contact their healthcare professional or Novo Nordisk on 1850 665 665.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)

Further information

www.novonordisk.ie

Customer Service

Novo Nordisk 1850 665 665 infoireland@novonordisk.com

Media

Mr Owen Treacy 01 862 9700 infoireland@novonordisk.com