

Urgent Field Safety Notice

NovoPen® Echo® and NovoPen® 5

Ref. 2016050310

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Important safety information

Dear Patient

Novo Nordisk A/S has detected that the insulin cartridge holder used in a number of NovoPen® Echo® and NovoPen® 5 batches may crack or break if exposed to certain chemicals in some household products, such as cleaning agents, sunscreen and food grease. 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 batches to contact Novo Nordisk in order to replace the cartridge holder, which is just one component of the pens, as some could be damaged. Please check your device batch number against the list of affected batches below.

A picture of the cartridge holder is shown below (Figure 1)



Figure 1. Cartridge holder used for NovoPen® Echo® and NovoPen® 5.

Description of the problem:

If the cartridge holder comes in contact with certain chemicals it can crack or break. The reason for the cracking is that the plastic materials used for the cartridge holders in the affected batches can be weakened if exposed to certain chemicals found in some household products such as cleaning agents, sunscreen and food grease.

When cleaning the device as described in Instructions For Use, cracking of the cartridge holder is extremely unlikely.

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

The warning symptoms of high blood sugar (hyperglycaemia) normally appear gradually and can be: flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; and losing your appetite, feeling or being sick (nausea or vomiting).

You might not experience any physical signs of high blood sugar, but only be able to see it in your blood sugar measurements.



Details of affected devices:

The affected NovoPen[®] Echo[®] and NovoPen[®] 5 batch numbers distributed in the UK are shown in below tables. Please note the batch number can differ very slightly on the pen and the box that it comes in.

NovoPen [®] Echo [®]		NovoPen [®] 5	
Batch number on carton	Batch number on pen	Batch number on carton	Batch number on pen
DUG0191	DUG0191	DVG1930-3	DVG1930
DUG0192	DUG0192	DVG2199-2	DVG2199
DUG0193	DUG0193	DVG3018-2	DVG3018
DUG1613	DUG1613	EVG0506-2	EVG0506
DUG1614	DUG1614	EVG0507-2	EVG0507
DUG1615	DUG1615	EVG0615-2	EVG0615
DUG1616	DUG1616	EVG0707-3	EVG0707
DUG1708	DUG1708	EVG0902-2	EVG0902
DUG1709	DUG1709	EVG2293-1	EVG2293
DUG1775	DUG1775	EVG2906-1	EVG2906
DUG1776	DUG1776	EVG2907-2	EVG2907
DUG1777	DUG1777	EVG2910-2	EVG2910
DUG1778	DUG1778	EVG3008-1	EVG3008
DUG2049	DUG2049	EVG3112-2	EVG3112
DUG2053	DUG2053	EVG6245-1	EVG6245
DUG2054	DUG2054	EVG6822-3	EVG6822
DUG2055	DUG2055	FVG7150-1	FVG7150
DUG2055-1	DUG2055	FVG7564-2	FVG7564
DUG2056	DUG2056	FVG7565-2	FVG7565
DUG2058-1	DUG2058	FVG7565-5	FVG7565
DUG2129-1	DUG2129	FVG7566-2	FVG7566
DUG2218-1	DUG2218	FVG7567-2	FVG7567
DUG2219-1	DUG2219	FVG7612-1	FVG7612
DUG2343-1	DUG2343	FVG7613-1	FVG7613
DVG1565-1	DVG1565	FVG7613-2	FVG7613
DVG1566-1	DVG1566	FVG7616-1	FVG7616
DVG1715-4	DVG1715	FVG7617-2	FVG7617
DVG2297-4	DVG2297	FVG8531-2	FVG8531
EVG2298-6	EVG2298	FVG8532-1	FVG8532
EVG2299-6	EVG2299	FVG8654-2	FVG8654
EVG2300-2	EVG2300	FVG8655-1	FVG8655
EVG2908-2	EVG2908	FVG8657-2	FVG8657
EVG2909-1	EVG2909	FVG8658-1	FVG8658
EVG2915-1	EVG2915	FVG8659-1	FVG8659

EVG3011-1	EVG3011		
EVG3011-3	EVG3011		
EVG3999-2	EVG3999		
EVG4253-3	EVG4253		
EVG5697-1	EVG5697		
EVG5698-2	EVG5698		
EVG5946-8	EVG5946		
EVG5962-1	EVG5962		
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		
FVG8998-1	FVG8998		

Table 1. List of affected NovoPen® Echo® and NovoPen® 5 batches in the UK.

You can find the batch numbers printed on NovoPen® Echo® and NovoPen® 5 pens and box as indicated below (Figures 2 and 3).

A



B



Figure 2. Red squares show where the batch number is located on (A) NovoPen® Echo® and (B) NovoPen® 5. Please note the pen will need to be dialled up in order to see the batch numbers. The NovoPen® Echo® comes in a red and blue colour, whereas a NovoPen® 5 can be blue or grey.



Figure 3. Red square shows where the batch number is located on the box.



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

What to do if you are using a NovoPen[®] Echo[®] and/or NovoPen[®] 5 with one of the above-mentioned batch numbers:

- Do **not** stop treatment without consulting your doctor.
- 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 health care provider and take appropriate action.
- In the event that you experience symptoms of too high blood sugar involving this product, contact your doctor for advice.
- To request a replacement cartridge holder, register your contact details (name, address, phone number, email and number of affected cartridge holders) either at the local Novo Nordisk website www.novonordisk.co.uk or contact the local Novo Nordisk Customer Care line on 0845 600 5055. Novo Nordisk will extend opening hours of the Customer Care line to include weekends to support patients. Opening hours will be 8am-8pm Mon-Fri and 8am-4pm Sat-Sun.
- You will receive an unaffected cartridge holder for your NovoPen[®] Echo[®] and/or NovoPen[®] 5 within 7 days. Upon receipt, you should attach the new cartridge holder and use as stated in Instructions For Use.
- Report any adverse events or complaints (including a damaged cartridge holder) to Novo Nordisk's Customer Care line on 0845 600 5055.

If you have any questions or concerns, please contact your XXXXXXXXXX pharmacist or Novo Nordisk's Customer Care line on 0845 600 5055. Opening hours will be 8am-8pm Mon-Fri and 8am-4pm Sat-Sun.

The safety of patients is of utmost importance for Novo Nordisk. We strive to produce and distribute the highest quality products for your use. We sincerely apologise for this unfortunate situation and the concerns and inconvenience it may cause.

Yours sincerely,

Dr Avidah Nazeri
Director of Clinical, Medical and Regulatory

Novo Nordisk Ltd

Further information

Customer Service

Novo Nordisk's Customer Care line 0845 600 5055. Novo Nordisk will extend opening hours of the Customer Care line to include weekends to support patients. Opening hours will be 8am-8pm Mon-Fri and 8am-4pm Sat-Sun.

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