# PATIENT ORGANISATION INFORMATION LETTER

05 July 2017

## Important safety information for people with diabetes in possession of NovoPen Echo® and/or NovoPen® 5

Novo Nordisk A/S has detected that the insulin cartridge holder used in a small number of NovoPen Echo® and NovoPen® 5 batches may crack or break if exposed to certain chemicals, for example certain cleaning agents. NovoPen Echo® and/or NovoPen® 5 devices are used by people with diabetes to inject their insulin.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected LOT/batch numbers to replace the cartridge holder.

A picture of the cartridge holder is shown in Figure 1.


**Figure 1.** Picture of cartridge holder used for NovoPen Echo® and NovoPen® 5.

### Description of the problem

If the cartridge holder comes in contact with certain chemicals it may crack or break. The reason for the cracking is that the plastic materials used for the cartridge holders in the affected LOT/batch numbers can be weakened if exposed to certain chemicals found, for example, in some cleaning products. When cleaning the pen as described in the Instructions For Use, there is no reason to believe that cracking of the cartridge holder will occur.

Using a pen with a cracked or broken cartridge holder could result in the device delivering a smaller than intended insulin dose leading to an increase in 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 (hyperglycaemia) normally appear gradually and can be: flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; loss of appetite or feeling or being sick (nausea or vomiting).
Patients may not experience any physical signs of high blood sugar levels, but may only see the high readings in their blood sugar measurements.

Novo Nordisk has already changed the material of the cartridge holder back to the original type, where the issue with cracked and broken cartridge holders was not seen.

This issue is being coordinated by pharmacists in Ireland. We are also making patients aware of the issue via appropriate networks including Diabetes Ireland and the Irish media.

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**Details of affected devices**

The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in Table 1. Please note the LOT/batch number can differ very slightly on the pen and 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 | | |

**Table 1.** List of affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers in Ireland

**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 2).

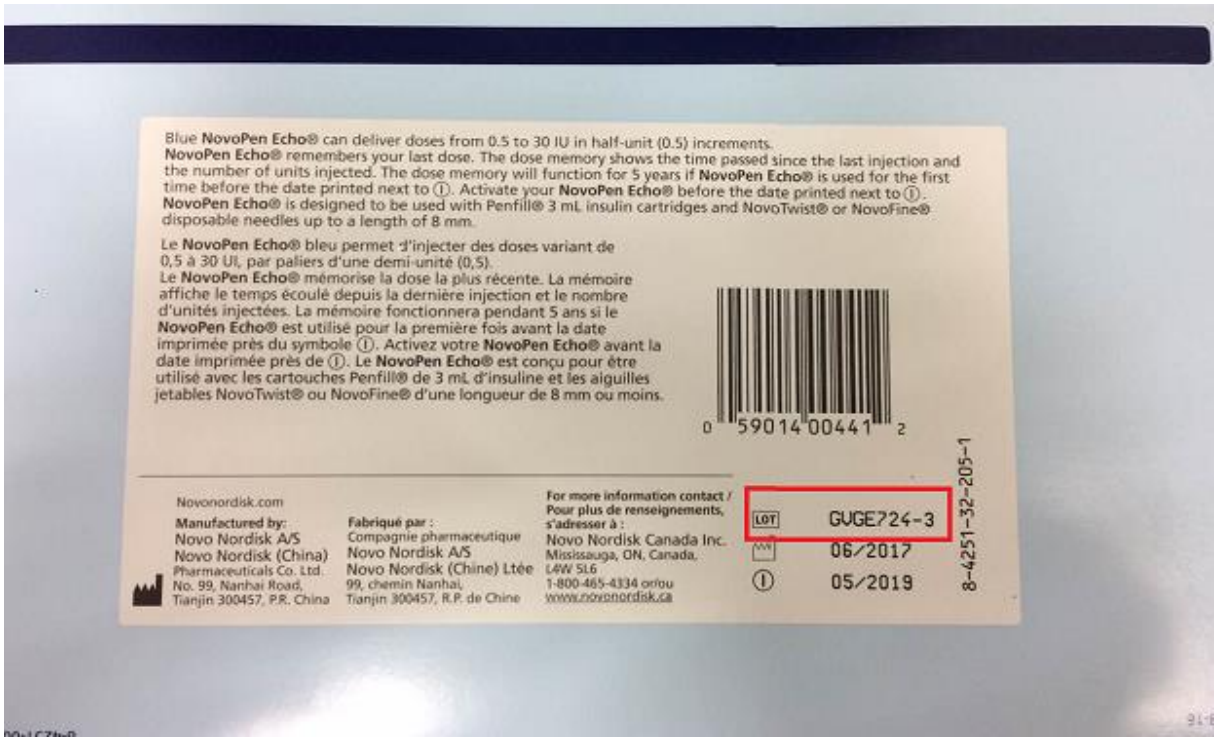


**Figure 2.** Red square shows where the LOT/batch number is located on a NovoPen Echo® and NovoPen® 5 e.g. the LOT/batch number on the above device is GVGE724-3

2. 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 3.

**A** **B**


**Figure 3.** Red squares show where the LOT/batch number is located on A) NovoPen Echo® and B) NovoPen® 5. e.g. the LOT/ 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 they can be confident that the pen will work as intended.

**What to do if a patient has a NovoPen Echo® and/or NovoPen® 5 with one of the above-mentioned LOT/batch numbers**

- Do **not** stop treatment without consulting their healthcare professional.
- Be attentive to blood sugar levels by looking for symptoms of hyperglycaemia. If symptoms occur, measure blood sugar levels as instructed by their healthcare professional and take appropriate action.
- In the event that a patient experiences symptoms of too high blood sugar levels involving this product, they should contact their healthcare professional for advice.
- Register contact details (name, address, phone number, email and number of affected cartridge holders) to order an unaffected cartridge holder for their NovoPen Echo® and/or NovoPen® 5:
  - via the Novo Nordisk corporate website www.novonordisk.com
  - by contacting Novo Nordisk on 1850 665 665 to
- The replacement cartridge holder should be attached and used as stated in the Instructions For Use, page 2.
- Report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

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.

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

Yours sincerely,

**Dr Donna Sexton**
**Clinical, Medical and Regulatory Manager - Ireland**

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IR/DV/0717/0052

# Information for your website
# Important safety information for people with diabetes in possession of NovoPen Echo® and/or NovoPen® 5

Novo Nordisk A/S has detected that the insulin cartridge holder used in a small number of NovoPen Echo® and/or NovoPen® 5 batches may crack or break if exposed to certain chemicals, for example certain cleaning agents. NovoPen Echo® and NovoPen® 5 are used by people with diabetes to inject their insulin.

When cleaning the NovoPen Echo® and NovoPen® 5 as described in the Instructions For Use, there is no reason to believe that cracking of the cartridge holder will occur.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected LOT/batch numbers to replace the cartridge holder.

A picture of the cartridge holder is shown in Figure 1.


**Figure 1.** Picture of cartridge holder used for NovoPen Echo® and NovoPen® 5.

**Details of affected devices:**
The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in Table 1. Please note the LOT/batch number can differ very slightly on the pen and 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 | | |

**Table 1.** List of affected NovoPen Echo® and NovoPen® 5 LOT/batches numbers in Ireland

**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 2).

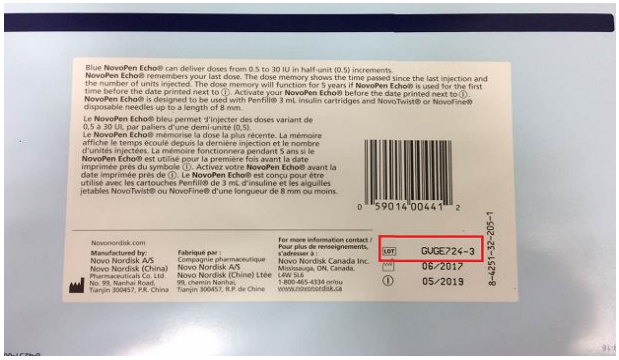


**Figure 2.** Red square shows where the LOT/batch number is located on a NovoPen Echo® and NovoPen® 5 e.g. the LOT/batch number on the device is GVGE724-3

2. 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 3.

**A** **B**


**Figure 3.** 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® is FVG7364.

Patients in possession of a NovoPen® Echo® and/or NovoPen® 5 device with one of the following batch numbers should register their contact details (name, address, phone number, email and number of affected cartridge holders) to order an unaffected cartridge holder for their NovoPen Echo® and/or NovoPen® 5:

- via the Novo Nordisk corporate website www.novonordisk.com
- by contacting Novo Nordisk on 1850 665 665 to

- The replacement cartridge holder should be attached and used as stated in the Instructions For Use, page 2.

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 they can be confident that the device will work as intended.

Report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

# Q&As for your patient helpline

**Product quality**

1. **What exactly is the issue with the pen?**

   A new type of cartridge holder was introduced in July 2014 to improve pen design. The purpose of the cartridge holder is to attach the insulin cartridge to the pen. The cartridge holder is removed every time a patient needs to load the pen with a new insulin cartridge. Thus, removing and replacing the cartridge holder is part of the normal use of a NovoPen Echo and/or a NovoPen® 5 for patients.

   A picture of the cartridge holder is shown below:

   
   

   However it is now known that if the new type of cartridge holder introduced in July 2014 comes into contact with certain chemicals, it may crack or break. The reason for the cracking is that the plastic materials used for the cartridge holders can be weakened if exposed to certain chemicals found, for example, in some cleaning products. When cleaning the device as described in the Instructions For Use, there is no reason to believe that cracking of the cartridge holder will occur. Using a pen with a cracked/broken cartridge holder may result in the pen not delivering the intended insulin dose, potentially leading to fluctuations in blood sugar levels.

2. **Which devices are affected?**

   NovoPen Echo® and NovoPen® 5 devices using this this type of cartridge holder are affected.

3. **What is the risk if I'm in possession of an affected pen?**

   The risk that a patient will experience high blood sugar levels over the lifetime of an affected pen is less than 0.1% i.e. less than 1 in 1000 patients will experience high blood sugar levels due to this. If a patient has a pen with one of the affected batch numbers he or she must register 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 to receive a replacement cartridge holder for the NovoPen Echo® and/or NovoPen® 5, which the patient should attach and use as stated in Instruction For Use, page 2. If the cartridge holder is defective (cracked or snaps broken off) the patient's healthcare professional should be contacted to agree on alternative medication

or an alternative method of delivering the patient's usual Novo Nordisk insulin until the new cartridge holder is received by the patient.

Patients should also report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

4. **How should the person with diabetes react if he or she experiences either an over or under dosing?**

In the event that the patient experiences symptoms of too low or too high blood sugar levels associated with the use of these devices, the patient must contact his or her healthcare professional for advice. Patients are trained in how to handle hypoglycaemia or hyperglycaemia (too low or too high blood sugar) and should act accordingly prior to contacting the doctor.

Patients should also report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

5. **Has Novo Nordisk received any adverse events related to the affected NovoPen Echo® and/or NovoPen® 5?**

Novo Nordisk has over the last year received approximately 50 non-serious adverse events where a patient experienced too high blood sugar levels and this could potentially be due to a faulty cartridge holder. The patients recovered in all cases.

6. **Have health authorities been informed about the issue?**

Yes, Novo Nordisk has informed all affected health authorities including the Health Products Regulatory Authority in Ireland.

7. **Have doctors and patients been informed about the affected products?**

Yes, Novo Nordisk is informing HCPs and patients in order to replace affected cartridge holders, through all of the approporiate channels including Diabetes Ireland, health authorities, Novo Nordisk website and the media.

**Replacement of product**

8. **If I am in possession of a NovoPen Echo® and/or NovoPen® 5 from the affected batches will I get a replacement product?**

If a patient has a device with one of the affected batch numbers he or she must:

- **Not** stop treatment without consultinh a healthcare professional
- Be attentive to blood sugar levels by checking them regularly and looking for symptoms of hyperglycaemia. If symptoms are noted, measure blood sugar levels as instructed by a healthcare professional and take appropriate action.
- In the event that symptoms of high blood sugar levels occur a healthcare professional should be contacted for advice.

The patient should register contact details (name, address, phone number, email and number of affected cartridge holders) to order an unaffected cartridge holder for their NovoPen Echo® and/or NovoPen® 5:

- via the Novo Nordisk corporate website www.novonordisk.com
- by contacting Novo Nordisk on 1850 665 665 to

- The replacement cartridge holder should be attached and used as stated in the Instructions For Use, page 2.

If the cartridge holder is defective (cracked or snaps broken off) the patient's healthcare professional should be contacted to agree on alternative medication until the new cartridge holder is received by the patient.

Patients should also report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com