**Urgent Field Safety Notice**

**NovoPen® Echo® and NovoPen® 5**

**Ref. 2016050310**

5 July 2017

# Important safety information

Dear Healthcare Professional

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 is already in contact with the MHRA regarding this issue.

Novo Nordisk urges diabetes patients 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.

A picture of the cartridge holder is shown in 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.

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.

Using a device with a cracked or broken cartridge holder could result in the device delivering a smaller than intended dose 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.

A patient might not experience any physical signs of high blood sugar (hyperglycaemia), but only be able to see it in on the 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 (Figure 2) and box (Figures 3) as indicated below.

The batch numbers are printed on NovoPen® Echo® and NovoPen® 5 as indicated below (Figure 2).

|  |  |
| --- | --- |
| **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® can be red or blue in colour, whereas a NovoPen® 5 can be blue or grey. | |

|  |  |
| --- | --- |
|  | |
| C:\Users\RCME\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\IMG_5442.jpg |  |
| **Figure 3.** Red square shows where the batch number is located on the box. | |

This issue is being coordinated through UK pharmacists. We are also contacting patients via all appropriate networks including patient groups and the UK media. All relevant information for patients can be accessed through the Novo Nordisk website.

**If you in your hospital or clinic are in possession of stock of NovoPen® Echo® and/or a NovoPen® 5 devices with the affected batches numbers, we kindly ask you to contact Alloga UK Limited to arrange their return on 01773 515124. Please contact Novo Nordisk for any other queries.**

If you have patients that contact you that are using NovoPen® Echo® and/or NovoPen® 5 with one of the above-mentioned batch numbers:

* Attached is an information letter that may be shared with any patients that discuss who may have one of the affected NovoPen® Echo® and/or NovoPen® 5 devices. In the letter, patients are asked to check if they use a NovoPen® Echo® and/or NovoPen® 5 device from the affected batches and, if so, to contact Novo Nordisk for a replacement of the cartridge holder. A replacement may take up to seven days to arrive.
* For patients using a NovoPen® Echo® or NovoPen® 5 device with a batch number **not** mentioned above, there is no reason for concern and they can continue their treatment as usual.

## Follow-up action

## Novo Nordisk will continue to monitor adverse events and complaints reported with the affected batches and will communicate if any new relevant information becomes available.

## Reporting

## It is important that all adverse drug events and device incidents occurring during treatment using NovoPen® Echo® or NovoPen® 5 are reported in accordance with the local national legislation on spontaneous reporting of device incidents and adverse events.

## Please report any complaints and adverse events. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## Company contact point

If you have any questions or concerns, please refer to the Novo Nordisk website [www.novonordisk.co.uk](http://www.novonordisk.co.uk) or contact Nordisk’s 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.

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,

Avideh Nazeri

Director of Clinical, Medical and Regulatory

## Novo Nordisk Ltd

## Further information

Novo Nordisk website [www.novonordisk.co.uk](http://www.novonordisk.co.uk)

Novo Nordisk’s Customer Care line on 0845 600 5055