Urgent Field Safety Notice
NovoPen® Echo®
Ref. 2016050310

05 Jul 2017

Important safety information

Dear Healthcare Professional
Cc: Chairman of Medical board and all relevant Head(s) of Department

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

Novo Nordisk urges diabetes patients using a NovoPen® Echo® from one of the affected batches to replace the cartridge holder as some could be damaged.

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

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

Description of the problem:
If the cartridge holder comes in contact with certain chemicals it could 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, for example, in some cleaning products. When cleaning the pen as described in Instruction For Use, there is no reason to believe that cracking of the cartridge holder will occur.

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/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

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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; losing your appetite, feeling or being sick (nausea or vomiting).

A patient might not experience any physical signs of high blood sugar, but only be able to see it in on the blood sugar measurements.

Details of affected devices:

The affected NovoPen® Echo® batch numbers distributed in Singapore is shown in below tables:

NovoPen® Echo®:

FVG8413-5

Table 1. List of affected NovoPen® Echo® batch in Singapore.

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

A

Figure 2. Red squares show where the batch number is located on A) NovoPen® Echo® E.g. the batch number on the NovoPen® Echo® to the left is FVG7364.

If you in your hospital or clinic are in possession of NovoPen® Echo® devices with the affected batches numbers we kindly ask you to contact Novo Nordisk to have these samples replaced.

If you have patients using NovoPen® Echo® and with the above-mentioned batch number:

- We kindly request your support to ensure that patients using NovoPen® Echo® from the affected batch are made aware of this potential issue and are urged to replace the affected cartridge holder with a new, unaffected version.

- Attached is an information letter to be distributed to patients who may have one of the affected NovoPen® Echo® device. In the letter, patients are asked to check if they use a NovoPen® Echo® device from the affected batches and if so, to contact Novo Nordisk for a replacement of the cartridge holder.

- For patients using a NovoPen® Echo® 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® 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 to Novo Nordisk's customer service, which can be reached at +65 6295 5518 or via email at SGAgree1@novonordisk.com

You may also report complete the voluntary adverse event reporting form to Health Sciences Authority (HSA) and submit by mail or fax to:

Adverse Event Reporting
Vigilance & Compliance Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01 Helios
Singapore 138667
Fax: (65) 6478 9069

Or email the voluntary report to hsa_productsafety@hsa.gov.sg

Company contact point

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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

Trine W. Lavrsen
Country Manager
Novo Nordisk Pharma (Singapore) Pte. Ltd.