

Urgent Field Safety Notice

NovoPen® Echo®

Ref. 2016050310

05 JUL 2017

Important safety information

Dear Patient

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® is used for insulin treatment by people with diabetes.

Novo Nordisk urges people with diabetes using a NovoPen® Echo® from one of the affected batches to replace the cartridge holder 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. Picture of cartridge holder used for NovoPen® Echo® .

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, for example, in some cleaning products. When cleaning the device as described in Instruction For Use, there is no reason to believe that cracking of the cartridge holder will occur.

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; 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® batch number distributed in Singapore is **FVG8413-5**

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 patients are in possession of a NovoPen® Echo® device with a 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 you are using a NovoPen® Echo® with one of the above-mentioned batch numbers:

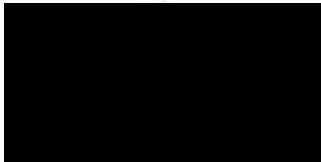
- Do **not** stop treatment without consulting your doctor.
- Be attentive to your blood sugar levels by looking for symptoms of hyperglycaemia. If you note these symptoms, measure your blood sugar levels as instructed by your health care provider and take appropriate action.
- In the event that you experience symptoms of too high blood sugar involving this product, contact your doctor for advice.
- Register contact details (name, address, phone number, email and number of affected cartridge holders) at the Novo Nordisk's corporate website www.novonordisk.com or contact Novo Nordisk Pharma Singapore in order to receive an unaffected cartridge holder for your NovoPen® Echo®, which you should attach and use as stated in Instruction For Use, page 3.

- Report any adverse events or complaints to Novo Nordisk's Customer Service, which can be reached at +65 6295 5518 or via email at SGAgree1@novonordisk.com

If you have any questions or concerns, please contact your doctor, pharmacist or Novo Nordisk Customer Service in the country where you are situated.

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.

Further information
Customer Service

Novo Nordisk Pharma +65 6295 5518
(Singapore) Pte. Ltd.
152, Beach Road, #17-04,
The Gateway East, 189721
Singapore

SGAgree1@novonordisk.com