

## Urgent Field Safety Notice

**NovoPen® Echo®**

**Ref. 2016050310**

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### **Important information for pharmacies in possession of NovoPen® Echo®**

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 the affected batch 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, against guidance in the Instructions For Use, 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 pen 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 can result in the device delivering a smaller than intended insulin dose leading to an increase in 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 you are in possession of a NovoPen® Echo® device with batch numbers **not** mentioned above, there is no reason for concern and the devices will work as intended and can be distributed to patients.

**What to do if you have stock of NovoPen® Echo® devices with the above-mentioned batch number:**

- Do not sell or hand out more of the affected devices.
- Return affected devices to Novo Nordisk or your wholesaler and order new devices from your wholesaler.

**What to do when patients come in with a NovoPen® Echo® device with the above-mentioned batch number:**

- In the event that the patient has experienced symptoms of too high blood sugar involving an affected device they should contact their doctor for advice. The doctor or the customer should 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](mailto:SGAgree1@novonordisk.com)
- Please ask the patient to register contact details (name, address, phone number, email and number of affected cartridge holders) at Novo Nordisk's corporate website [www.novonordisk.com](http://www.novonordisk.com) or contact the local Novo Nordisk Customer Service in order to receive an unaffected cartridge holder for his or her NovoPen® Echo®, which the patient should attach and use as stated in Instruction For Use, page 3.
- If you have any questions or concerns, please contact Novo Nordisk Customer Service at +65 6295 5518 or via email at [SGAgree1@novonordisk.com](mailto:SGAgree1@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.

Yours sincerely,



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**Further information**  
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