



## NovoMix® 30 Penfill®

### Important safety information for diabetes patients using NovoMix® 30 Penfill®

October 29<sup>th</sup>, 2013

Novo Nordisk is recalling 3 batches of NovoMix® 30 Penfill® in Ireland. NovoMix® 30 (biphasic insulin aspart 30) is indicated for the treatment of diabetes.

The purpose of this communication is to:

- Explain the reason for the recall,
- State what batches of NovoMix® 30 Penfill® are affected by the recall and where you can locate them on your medicine,
- Ensure that you can get replacement NovoMix® 30 Penfill®, if you have NovoMix® 30 Penfill® in your possession that is affected by this recall.

The reason for the recall is that a small number of units in these batches do not meet the specifications for insulin strength, which may lead to your blood sugar level becoming higher or lower than expected.

The batch numbers of affected NovoMix® 30 Penfill® which have been distributed in Ireland are: **CS6C411, CS6C628 and CS6D422.**

The batch numbers are printed on the cartridge for NovoMix® 30 Penfill®.

If you are using NovoMix® 30 Penfill® with a batch number not mentioned above or if you are using NovoMix® FlexPen® you can continue your treatment as usual.

If you are using a product with one of the above-mentioned batch numbers you should take special precautions as described below until you are switched to a product from unaffected batches.

#### Risk of high or low blood sugar

There is a risk that the number of insulin units you receive in an injection will either be lower or higher than the dose selected. This could lead to high blood sugar (hyperglycaemia) or low blood sugar (hypoglycaemia). For information on symptoms of hyperglycaemia and hypoglycaemia, see below.

As it is not possible to visually identify the products which do not meet the specifications, and as a safety precaution, the Irish Medicines Board together with Novo Nordisk have initiated a recall of all products in the affected batches in Ireland.

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**What to do if you are using NovoMix® 30 Penfill® with one of the above-mentioned batch numbers:**

- Return your NovoMix® 30 Penfill® with the above mentioned batch numbers to your pharmacy.
- Ask your pharmacist for a replacement from a batch not affected by the recall.
- **Do not stop treatment without consulting your doctor.**
- Measure your blood sugar level frequently to ensure it is well controlled.
- In the event that you experience symptoms of too low or too high blood sugar involving this product, contact your doctor for advice.
- Report any adverse drug reactions to Novo Nordisk by telephoning 1850 665 665 or via email at [complaintireland@novonordisk.com](mailto:complaintireland@novonordisk.com).

**Symptoms of high and low blood sugar**

The symptoms of high blood sugar (hyperglycaemia) are increased amount and frequency of urination, excessive thirst, nausea, tiredness or vomiting. The symptoms of low blood sugar (hypoglycaemia) are drowsiness, palpitations, sweating, pallor, numbness, headaches, irritability, fatigue, slurred speech, "pains and needles" sensation on your skin or coma.

Yours sincerely,



**Donna Sexton**  
**Clinical, Medical and Regulatory Manager**

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**Further information**

**Customer Service**

Customer Care line

1850 665 665

[info@novonordisk.ie](mailto:info@novonordisk.ie)