**NovoMix® 30 Penfill®**
**EU/1/00/142/004**

# Novo Nordisk Ireland is recalling three batches of NovoMix® 30 Penfill® (biphasic insulin aspart 30) due to a potential quality issue - too low or too high insulin strength

29th October 2013

Dear Healthcare Professional,

Novo Nordisk, in agreement with the European Medicines Agency and the Irish Medicines Board (IMB), would like to inform you of the following:

In Ireland, three batches of NovoMix® 30 Penfill® are being recalled to patient level (starting on October 29th, 2013) due to the risk that a small number of these cartridges have a too low or a too high insulin aspart strength.

The purpose of this letter is:

(i) to inform you of the background to the recall;
(ii) to describe the manner in which we expect this patient level recall to take place - pharmacists have been asked to identify and contact patients who were dispensed product from the affected NovoMix® 30 Penfill® batches and they will request that the patient returns the affected product to the pharmacy for replacement product from an unaffected batch;
(iii) to provide you with a communication (attached) that you can share with your patients, in the event that a patient has a concern regarding the recall or the process for obtaining the replacement stock.

The batch numbers and expiry dates of the NovoMix® 30 Penfill® being recalled in Ireland are:

| Batch number | Expiry date |
|---|---|
| CS6C411 | 08/2014 |
| CS6C628 | 09/2014 |
| CS6D422 | 10/2014 |

**Please note that NovoMix® 30 FlexPen® is unaffected by this recall.**

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

**Summary**

- Novo Nordisk estimates that 0.14% of the cartridges in the above-mentioned batches may not meet the specification for insulin strength, and this may lead to the patient's blood sugar level becoming higher or lower than expected.

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IR/NM30/1013/0016
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- These batches were first distributed in Ireland on May 20th, 2013.

- As of 28th October 2013, no adverse events as a consequence of this quality issue have been reported to Novo Nordisk Ireland.

- However, to minimise any potential risk, a patient-level recall has been initiated for these three NovoMix® 30 Penfill® batches. Pharmacists have been requested to identify and contact all patients who have been dispensed these batches so that any patients with unused or partially used cartridges from these batches can return them to their pharmacy for a replacement cartridge.

- Unaffected batches are immediately available. Please also find enclosed a letter which can be used to support your patients should they have a query in relation to the recall or the return of affected NovoMix® 30 Penfill® to their pharmacy. In the letter patients are asked to check if they are in possession of NovoMix® 30 Penfill® from the affected batches and if so, to return the affected product to their pharmacist for replacement with NovoMix® 30 Penfill® from a batch not affected by the recall.

- This recall only concerns the above-mentioned batches of NovoMix® 30 Penfill®**.** Patients using a NovoMix® 30 Penfill® product with a batch number <u>not</u> mentioned above can continue using their medicine.

**Further information on the safety concern and recommendations**

**Safety concern: Out-of-specification biphasic insulin aspart 30**
NovoMix® 30 is indicated for the treatment of diabetes mellitus in adults, adolescents, and children aged 10 years and above. NovoMix 30® (biphasic insulin aspart 30) is a biphasic suspension of the insulin analogue, insulin aspart. The suspension contains rapid-acting and intermediate-acting insulin aspart in the ratio 30/70.

The batches affected by this quality issue will visually appear normal, and any incorrect concentration of the insulin and the preservatives will be impossible to detect by the end user. Worst-case scenarios have been defined as a concentration of insulin as low as 50% of the labelled concentration and as high as 150% of the labelled concentration.

Injection of NovoMix® 30 containing around 50% of the intended dosage may lead to some degree of hyperglycaemia in patients with type 1 or type 2 diabetes mellitus. Injection of NovoMix® 30 containing 150% of the intended dosage may, in a worse case scenario, lead to severe hypoglycaemia.

In general, people with diabetes are well trained and aware of warning signs and the symptoms of both hypoglycaemia and hyperglycaemia. This will, in most situations, guide patients to measure their blood glucose level and, based on that measurement, patients, caregivers, and/or health care professionals will be able to take appropriate action. However, in some situations the development of severe hypoglycaemia may be fast and be without significant warning symptoms.

**Follow-up action**
Novo Nordisk, in agreement with the European Medicines Agency and the IMB, will continue to monitor any adverse events reported for this product and ensure that all appropriate measures are taken. We are also working to identify and implement permanent technical solutions to prevent a reoccurrence of this issue. Novo Nordisk will communicate with you if any new relevant information becomes available.

We kindly ask you to report all adverse drug reactions to the Irish Medicines Board or directly to Novo Nordisk.

**Reporting**
It is important that all adverse drug reactions occurring during treatment with NovoMix® 30 are reported to the Irish Medicines Board or to Novo Nordisk directly. Information about adverse event reporting is available at www.imb.ie Adverse events should be reported to the Novo Nordisk Medical department; Tel: 1 850 665 665.

**Company contact point**
We apologise for any inconvenience that this issue may cause. If you require any further information related to this patient-level recall, please contact our Customer Care line on 1850 665 665 or info@novonordisk.ie

Yours sincerely

Dr Donna Sexton
Clinical, Medical and Regulatory Manager