

# DRUG ALERT

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Patient and Pharmacy Level Recall

Date: 25 October 2013

EL (13)A/25

Our Ref: MDR 63-10/13

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Dear Healthcare Professional,

### **Novo Nordisk A/S**

**NovoMix 30 Penfill, 100U/ml, 3ml, Suspension for Injection** EU/1/00/142/004

**NovoMix 30 FlexPen , 100U/ml, 3ml, Suspension for Injection** EU/1/00/142/009  
**(Soluble insulin aspart / protamine insulin aspart 30% / 70%)**

Novo Nordisk A/S is recalling the batches listed in the table in Appendix 1 due to the possibility of a very small number of cartridges within each batch containing too much or too little insulin. We understand that the percentage of cartridges affected is approximately 0.14%.

Pharmacists are asked to quarantine any remaining stock from these batches. Patients who may have received the affected batches should be contacted and asked to check their supply. If they have any affected batches, they should be advised to contact their GP to request a new prescription and then return any stock from these batches only to their local pharmacy. **Please see Appendix 2 for advice to patients and healthcare professionals**

Remaining stock of the affected batches should be returned to the original supplier for credit. For enquiries relating to stock returns please contact [ncommercialopps@novonordisk.com](mailto:ncommercialopps@novonordisk.com), tel 01293 762091

For medical information enquiries, please contact [CustomerCare@novonordisk.com](mailto:CustomerCare@novonordisk.com), tel 0845 600 5055

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Alison Bunce  
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**London**  
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**APPENDIX 1: Affected batches**

**Novomix 30 Penfill, Distributed in the UK by Novo Nordisk Ltd**

Batch number	Expiry date	Pack size	Date of first distribution
CS6D422	Oct 2014	5 x 3ml	04 Jun 2013
CS6C628	Sep 2014	5 x 3ml	12 Apr 2013
CS6C411	Aug 2014	5 x 3ml	26 Mar 2013

**Novomix 30 FlexPen, Parallel Distributed in the UK**

Batch number	Expiry Date	Pack size	Date Shipped
CP50912	Oct 2014	5 x 3ml	04 Jun 2013
CP50750	Jul 2014	5 x 3ml	03 May 2013
CP50639	Jul 2014	5 x 3ml	16 Apr 2013
CP51706	Jan 2015	5 x 3ml	01 Oct 2013
CP50940	Oct 2014	5 x 3ml	28 Jun 2013
CP50928	Oct 2014	5 x 3ml	25 Jun 2013
CP50903	Oct 2014	5 x 3ml	04 Jun 2013
CP50914	Oct 2014	5 x 3ml	24 May 2013
CP50640	Jul 2014	5 x 3ml	16 Apr 2013
CP51095	Oct 2014	5 x 3ml	28 Jun 2013
CP50904	Oct 2014	5 x 3ml	07 Jun 2013
CP50650	Jul 2014	5 x 3ml	19 Apr 2013
CP51098	Oct 2014	5 x 3ml	28 Jun 2013
CP50915	Oct 2014	5 x 3 ml	29 May 2013
CP50412	Jul 2014	5 x 3ml	20 Mar 2013
CFG0003	Sept 2014	5 x 3ml	12 Jun 2013
CFG0002	Sept 2014	5 x 3ml	30 May 2013
CFG0001	Sept 2014	5 x 3ml	24 May 2013
CP50902	Oct 2014	10 x 3ml	31 May 2013
CP50749	Jul 2014	5 x 3ml	06 May 2013
CP50393	Jul 2014	5 x 3ml	08 Mar 2013
CP50950	Oct 2014	5 x 3ml	02 Jul 2013

CP51025	Oct 2014	5 x 3ml	21 Jun 2013
CP50751	Jul 2014	5 x 3ml	14 May 2013
CP50375	Jul 2014	5 x 3ml	15 Mar 2013
CP50420	Jul 2014	5 x 3ml	15 Mar 2013
CP51097	Oct 2014	5 x 3ml	28 Jun 2013
CP50641	Jul 2014	5 x 3ml	15 Apr 2013
CP51096	Oct 2014	10 x 3ml	28 Jun 2013
CP50392	Jul 2014	10 x 3ml	15 Mar 2013

## APPENDIX 2: ADVICE TO PATIENTS AND HEALTHCARE PROFESSIONALS

### What is the advice to patients who are taking these medicines?

- Do not stop insulin treatment without consulting your doctor as it helps to control your blood sugar level.
- If you are using a NovoMix 30 FlexPen or NovoMix 30 Penfill cartridges with a batch number not mentioned above you can continue treatment as usual.
- If you are using a FlexPen or Penfill cartridge that has an affected batch number on it you should consult your GP or nurse to make arrangements for a new supply as soon possible.
- In the meantime:
  - continue to use your insulin
  - measure your blood sugar level frequently to ensure it is well controlled
  - be alert for signs and symptoms of hypoglycaemia (too little blood sugar) or hyperglycaemia (too much blood sugar)
  - Keep in contact with an adult who can get medical help for you if necessary
- If you experience any difficulties with your blood glucose control seek medical attention as appropriate.
- When new supplies have been obtained, return the affected products to your pharmacy

### What is the advice to pharmacists?

- Patients using a NovoMix 30 Penfill cartridges or a NovoMix 30 FlexPen that has one of the 33 affected batch numbers on it may be at increased risk of hypoglycaemia or hyperglycaemia.
- The number of affected products present at patient level is thought to be very small.
- Patients may attend the pharmacy with new prescriptions for NovoMix 30 Penfill cartridges or NovoMix 30 FlexPens
- Advise the patient to start using the new supply of FlexPens or Penfill cartridges immediately and return the affected cartridges to the pharmacy.
- Advise the patient to monitor his or her blood glucose levels closely while switching to the newly prescribed FlexPen or Penfill cartridges, and to be alert for symptoms and signs of hypoglycaemia or hyperglycaemia.

- Where for whatever reason no supply of replacement stock of NovoMix 30 Penfill cartridges or NovoMix 30 FlexPens can be made, advise the patient to continue to use the affected cartridges and to monitor their blood glucose levels carefully, be alert for signs and symptoms of hypoglycaemia or hyperglycaemia and ensure they remain in contact with an adult who can offer help if needed and see your GP or specialist as soon possible.

### **What is the advice to GPs?**

- Patients using a NovoMix 30 Penfill cartridge or a NovoMix 30 FlexPen that has one of the 33 affected batch numbers on it may be at increased risk of hypoglycaemia or hyperglycaemia.
- The number of affected Penfill cartridges and FlexPens present at patient level is thought to be very small.
- At this point there should be enough replacement stock available, if a patient reports having a Penfill cartridge or FlexPen that has one of the 33 affected batch numbers on it, supply a new prescription for NovoMix 30 Penfill or NovoMix 30 FlexPen that can be filled from non-affected batches and advise the patient to start using the new supply of product immediately.
- Advise the patient to monitor his or her blood glucose levels closely while switching to the newly prescribed NovoMix30 cartridges or FlexPens, and to be alert for symptoms and signs of hypoglycaemia or hyperglycaemia. Ensure the patient has an adequate supply of testing strips
- Instruct the patient not to use any remaining Penfill cartridges or Flexpens that are affected and to return them to the pharmacy.