

Notice Information: - Recall
29 October 2013

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Active Substance:
- d) Reference:

e) Serial/Batch Number & Expiry Date:

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Batch number

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Expiry date

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CS6C411

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08/2014

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08/2014

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CS6C628

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<td style="border-bottom: rgb(127,127,127) 1pt solid; padding-bottom: 0cm; background-color: transparent; border-top-color: rgb(236,233,216); padding-left: 5.4pt; width: 87.9pt; padding-right: 5.4pt; height: 5.65pt; border-left-color: rgb(236,233,216); border-right: rgb(127,127,127) 1pt solid; padding-top: 0cm" valign="top" width="117">

09/2014

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CS6D422

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<td style="border-bottom: rgb(127,127,127) 1pt solid; padding-bottom: 0cm; background-color: transparent; border-top-color: rgb(236,233,216); padding-left: 5.4pt; width: 87.9pt; padding-right: 5.4pt; height: 5.6pt; border-left-color: rgb(236,233,216); border-right: rgb(127,127,127) 1pt solid; padding-top: 0cm" valign="top" width="117">

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10/2014

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f) Product Classification: Prescription-only Medicine

g) Authorisation Number: EU/1/00/142/004

h) Authorisation Holder: Novo Nordisk A/S,
Novo Alle,
Bagsvaerd,
Denmark

i) Prescription Required: Yes

j) Recall Classification: Wholesale, pharmacy and patient level

Part 2. Target Audience

a) Target Audience: Patients, Healthcare Professionals, Wholesalers

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board today confirms that, in line with the European Medicines Agency (EMA) recommendation, it is working to ensure the recall of three batches of the diabetes medicine NovoMix 30 Penfill, in Ireland.

The batches are being recalled as a result of manufacturing problems, identified during the filling of the cartridges within the pens. This has resulted in a small percentage of pens of Novomix 30 Penfill containing too high or too low amounts of insulin.

Three implicated batches of Novomix 30 Penfill have been distributed to pharmacies and patients in Ireland and recall letters were issued by the Marketing Authorisation Holder, Novo Nordisk A/S, to wholesalers and pharmacists on 29th October 2013

The affected batch numbers are:

CS6C411, expiry date 08/2014

CS6C628, expiry date 09/2014

CS6D422, expiry date 10/2014

These batches were first distributed in Ireland from May 20th 2013 onwards

Part 4. Action to be taken

a) Action to be taken:

Information for Patients

Patients will be contacted by their pharmacist to ensure the return of any unused or partially used units from the above-listed batches.

If you have not as yet been contacted, please check the batch number of the cartridge(s) currently in your possession

If you are in the possession of a pack from an affected batch, please return it to your pharmacy, where you will receive a replacement, unaffected pack

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

Please click on the link below for a letter from Novo Nordisk, intended for patients

[NovoMix 30 Penfill Patient letter](#)

Specific information for Pharmacists

All pharmacists registered in Ireland have been sent a recall letter via email on October 29th 2013, which details the steps to be taken to ensure an effective recall to pharmacy and patient level can occur. The letter is available at the below link.

[NovoMix 30 Penfill Pharmacy recall letter](#)

Information for Prescribers and other Healthcare Professionals

The relevant healthcare professionals will be sent a Direct Healthcare

The relevant healthcare professionals will be sent a Direct Healthcare Professional Communication by Novo Nordisk, to inform them of the recall and to provide information which can be shared with patients, should they have concerns regarding the recall. This letter is available at the below link.

[NovoMix 30 Penfill DHPC](#)

[Specific information for Wholesalers](#)

Wholesalers which received the above-listed batches have also been sent a recall letter on October 29th 2013; a copy of which can be found at the below link.

[NovoMix 30 Penfill Wholesaler letter](#)

Part 5. Enquiries

- a) All enquiries should be made to:

Further Information can be found at the following locations

www.ema.europa.eu

www.novonordisk.ie