Notice Information: - Recall - 29/10/2013

Title:

Recall of Three batches of NovoMix 30 Penfill to Patient Level in Ireland

Product:

NovoMix 30 Penfill 100U/ml (biphasic insulin aspart) Suspension for Injection in Cartridge

Reference:

QDR-H-13-568

Authorisation Number:

EU/1/00/142/004

Product Classification:

Prescription-only Medicine

Active Substance:

Insulin aspart

Serial / Batch Number(s) & Expiry Date:

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

Authorisation Holder:

Novo Nordisk A/S,
Novo Alle,
Bagsvaerd,
Denmark

Target Audience:

Patients, Healthcare Professionals, Wholesalers

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

Prescription Required:

Yes

Recall Classification:

Wholesale, pharmacy and patient level

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 numberof the cartridge(s) currently in your posession
- 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 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

Further Information:

Further Information can be found at the following locations

www.ema.europa.eu

www.novonordisk.ie