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Batches of the insulin medicine NovoMix 30 FlexPen and Penfill to be recalled

Patients using medicine from the affected batches should be switched to products from unaffected batches or alternative treatment

The European Medicines Agency is giving recommendations on how to deal with a recall of some batches of the diabetes medicine NovoMix 30 FlexPen and Penfill. The affected batches are being recalled because of a manufacturing problem during the filling of the cartridges, which resulted in some batches of NovoMix 30 containing too high or too low amounts of insulin units per millilitre.

According to information from the marketing authorisation holder, NovoNordisk A/S, it appears that only a small percentage of cartridges (0.14%) contain a wrong amount. However, in the affected cartridges the level of insulin may vary between 50% and 150% of the labelled insulin units, which could lead to hypoglycaemia or hyperglycaemia.

The European Medicines Agency therefore recommends that patients using NovoMix 30 FlexPen/Penfill from the affected batches be switched to products from unaffected batches or, if such batches are not available, to alternative treatment.

Patients or carers may themselves check the batch number printed on the NovoMix 30 FlexPen or the NovoMix 30 Penfill to see if their medicine is affected. If the batch number on their pen or cartridge does not correspond to any of the batch numbers listed below there is no concern.

Patients who have NovoMix 30 FlexPen/Penfill products from the affected batches should make an appointment with their doctor or nurse for switching treatment as soon as it is feasible.

It is important that these patients do not stop their treatment. Until contact with a healthcare professional has taken place, patients are advised to continue their treatment and to measure their blood glucose levels frequently to ensure adequate blood sugar control. Patients who experience symptoms of hypo- or hyperglycaemia should contact a healthcare professional.

As Member States are affected differently, depending on available stock of unaffected NovoMix 30 FlexPen/Penfill or alternative treatments, actions taken at national level may differ. More information on how this recall will be implemented in each Member State will be provided by the National Competent Authorities.

The European Medicines Agency is monitoring the situation closely and will ensure that appropriate measures are being taken by the company, including immediate corrective actions as well as

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permanent technical solutions to prevent reoccurrence. All remaining units of the affected batches in Novo Nordisk control have been quarantined.

The numbers of the affected NovoMix 30 FlexPen batches are: CP50912, CP50750, CP50639, CP51706, CP50940, CP50928, CP50903, CP50914, CP50640, CP51095, CP50904, CP50650, CP51098, CP50915, CP50412, CFG0003, CFG0002, CFG0001, CP50902, CP50749, CP50393, CP50950, CP51025, CP50751, CP50375, CP50420, CP51097, CP50641, CP51096 and CP50392.

The numbers of the affected NovoMix 30 Penfill batches are: CS6D422, CS6C628 and CS6C411.

The batch numbers are printed on the pen for NovoMix 30 FlexPen and on the cartridge for NovoMix 30 Penfill.

More about the medicine

NovoMix is a diabetes medicine that contains the active substance insulin aspart. It is available in a range of suspensions for injection in cartridges (Penfill) and prefilled pens (FlexPen).

NovoMix 30 contains 30% soluble (rapid-acting) insulin aspart and 70% protamine-crystallised (intermediate-acting) insulin aspart. It can be used in patients aged 10 years or over.

The other strengths of NovoMix are not affected.

NovoMix received an EU-wide marketing authorisation in August 2000. The batches affected by the quality defect have been distributed in the following Member States: Austria, Belgium, Czech Republic, Denmark, France, Germany, Iceland, Ireland, Luxemburg, Netherlands, Norway, Slovakia and United Kingdom. However, other countries in the EU might have received the affected batches through parallel distribution.

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