Think Medicines!

NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Issue 23
October 2017

Safety

Diabetes: Insulin safety and SGLT2 inhibitors

Insulin pens: NovoPen Echo and NovoPen 5 (certain batches) - risk of hyperglycaemia due to cartridge holder weakening when exposed to certain household chemicals

In July 2014, a redesigned cartridge holder for NovoPen Echo and NovoPen 5 was implemented to improve robustness. However, the redesigned cartridge holder can become weakened if it is exposed to chemicals in cleaning agents, sunscreen and food grease, and the snaps keeping the cartridge holder in place may crack or break off.

There are 3 types of fault that can occur: 'Snap cracked', 'One snap broken off', 'Both snaps broken off'.

In April 2016 Novo Nordisk decided to change production back to the original cartridge holder so that in future all products would be produced with the original cartridge holder. This was effective from 1st September 2016. Novo Nordisk issued an FSN in July 2017 to recall affected cartridge holders distributed through wholesalers between 22nd July 2014 to 16th June 2017. **Patients prescribed/dispensed a NovoPen Echo or NovoPen 5 during this time frame should be contacted to confirm if they are using a pen from an affected batch.**

Advice for patients using a NovoPen Echo and/or NovoPen 5 with one of the affected batch numbers:

- Do not stop treatment without consulting your doctor.
- Be attentive to your blood sugar levels by checking them regularly and looking for symptoms of hyperglycaemia. If you note these symptoms, measure your blood sugar levels as instructed by your health care provider and take appropriate action.
- In the event that you experience symptoms of too high blood sugar involving this product, contact your doctor for advice.
- To request a replacement cartridge holder, the patient should register your contact details (name, address, phone number, email and number of affected cartridge holders) either via the website www.novonordisk.co.uk or contact the Novo Nordisk Customer Care line on 0845 600 5055. Opening hours will be 8am-8pm Mon-Fri and 8am-4pm Sat-Sun.
- The patient will receive an unaffected cartridge holder for their NovoPen® Echo® and/or NovoPen® 5 within 7 days. Upon receipt, you should attach the new cartridge holder and use as stated in the Instructions For Use.

Risk of severe harm and death due to withdrawing insulin from pen devices

NHS Improvement is aware of patient safety incidents involving healthcare professionals, using insulin syringes and needles to extract insulin directly from pen devices or refill cartridges. This is dangerous and should not happen.

All healthcare professionals supporting the administration of insulin to patients in their own home or in a care home setting should be trained and competent in using insulin pens.

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Minimising the risk of medication errors when using high strength, fixed combination or biosimilar insulin products

Several new insulin products are now on the market. It is likely that further such insulin products will come to market over the next few years.

To prevent a patient being inadvertently given the wrong insulin, insulin must be prescribed by brand and not generically.

Healthcare professionals and patients need to understand the insulin strength of these products and how to use them correctly to minimise the risk of medication errors such as the wrong insulin dose being administered.

Advice for healthcare professionals:

Before starting/continuing treatment on the advice of another healthcare professional, a insulin product including high strength, fixed combination or biosimilar insulin:

- Consult the summary of product characteristics and any educational material available.
- Ensure that patients read and understand the patient leaflet and any patient education material.
- Ensure that patients receive appropriate training on the correct use of the product and injection device.
- Give patients a patient booklet and adult insulin passport.
- Warn patients only to use insulin as they have been trained because using it any other way may result in a dangerous overdose or underdose.
- Monitor glucose levels closely after starting a new treatment and in the following weeks. You may need to adjust doses and timing of concurrent rapid acting or short acting insulin products and other antidiabetic treatments.

SGLT2 inhibitors: Updated advice on increased risk of lower-limb amputation (mainly toes)

Canagliflozin may increase the risk of lower-limb amputation (mainly toes) in patients with type 2 diabetes. It is not yet clear if this is a class effect with the risk extended to include dapagliflozin and empagliflozin.

Advice for healthcare professionals:

- Carefully monitor patients receiving canagliflozin who have risk factors for amputation, such as poor control of diabetes and problems with the heart and blood vessels.
- Consider stopping canagliflozin if patients develop foot complications such as infection, skin ulcers, osteomyelitis, or gangrene.
- Advise all diabetic patients including those receiving any sodium-glucose co-transporter 2 (SGLT2) inhibitor, including dapagliflozin and empagliflozin, about the importance of routine preventive foot care and adequate hydration.

Report any suspected side effect with SGLT2 inhibitors or any other medicine (dependent on Black Triangle status) on a Yellow Card.