

MHRA Drug Safety
Updates can be found
at the following [link](#).

New higher strength Humalog® 200 units/ml KwikPen™

In order to minimize medication errors.

- Insulin lispro 200 units/ml solution for injection should ONLY be administered using the Humalog 200 units/ml pre-filled pen (KwikPen).
- When switching from one Humalog strength to another, the dose does not need to be converted. Unnecessary dose conversion may lead to under/over dosing and resultant hyper/hypoglycaemia.
- When prescribing Humalog KwikPen, please ensure that the correct strength is clearly written on the prescription.
- Humalog 200 units/ml KwikPen should be reserved for patients requiring more than 20 units of rapid-acting insulin per day.
- The Humalog 200 units/ml KwikPen carton and pen have been designed to visually differentiate the product from the Humalog 100 units/ml KwikPen.

https://assets.digital.cabinet-office.gov.uk/media/5707b9bfe5274a14d9000053/Humalog_DHPC_sent_25_March_2016.pdf

Metformin & Reduced Renal Function

Metformin has now been contraindicated in the US by the Food and Drug Administration (FDA) in patients who have a reduced renal function with an eGFR <30 mL/min.

NICE currently recommends for type 2 diabetes in adults (NG23) that the dose of metformin should be reviewed if eGFR less than 45mL/min and to avoid if eGFR is less than 30mL/min.

SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis (DKA)

The MHRA are advising health care professionals to test for raised ketones in patients with ketoacidosis symptoms, who are taking SGLT2 inhibitors **even if plasma glucose levels are near-normal**. SGLT2 inhibitors include: **Canagliflozin, Dapagliflozin and Empagliflozin**. Serious, life-threatening, and fatal cases of DKA have been reported in patients taking an SGLT2 inhibitor. In several cases, blood glucose levels were only moderately elevated (e.g. <14mmol/L) representing an atypical presentation for DKA, which could delay diagnosis and treatment.

Advice for health Care Professionals:

- Inform patients of the signs of diabetic ketoacidosis (DKA) and advise them to seek immediate medical advice if they develop any of these symptoms (e.g. rapid weight loss, feeling sick or being sick, stomach pain, fast and deep breathing, sleepiness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat).
- Discuss the risk factors of DKA with patients.
- Discontinue treatment with the SGLT2 inhibitor immediately if DKA is suspected or diagnosed.
- Do not restart treatment with any SGLT2 inhibitor in patients who experienced DKA during use, unless another cause for DKA was identified and resolved.
- Hold treatment with the SGLT2 inhibitor in patients who are in hospital for major surgery or acute serious illnesses; restart once the patient's condition has stabilised.

Canagliflozin: increased risk of lower extremity amputations in high cardiovascular risk patients

Consider stopping canagliflozin if a patient develops a significant lower limb complication (e.g. skin ulcer, osteomyelitis, or gangrene), at least until the condition has resolved, and continue to monitor the patient closely.

Carefully monitor patients receiving canagliflozin who have risk factors for amputation.

Advise and monitor all patients for signs and symptoms of water or salt loss; ensure patients stay sufficiently hydrated to prevent volume depletion in line with recommendations in the product information; note that diuretics can exacerbate dehydration.

Start treatment for foot problems (e.g. ulceration, infection, or new pain or tenderness) as early as possible and continue to follow standard treatment guidelines for routine prevention.

Canagliflozin and Dapagliflozin & the risk of acute kidney injury

The U.S. Food and Drug Administration (FDA) has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin and dapagliflozin.

It is recommended that healthcare professionals assess kidney function prior to starting canagliflozin or dapagliflozin and monitor periodically thereafter. If acute kidney injury occurs, promptly discontinue the drug and treat the kidney impairment.



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Clinical Commissioning Group

Safety

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