

ERTUGLIFLOZIN film-coated tablets (Steglatro® ▼) as monotherapy or with metformin for treating type 2 diabetes

The Pan Mersey Area Prescribing Committee recommends the prescribing of ERTUGLIFLOZIN film-coated tablets (Steglatro® ▼) as monotherapy or with metformin for treating type 2 diabetes in accordance with NICE TA572.

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NICE technology appraisal (TA) 572 (27 March 2019)^[1] states:

- > Ertugliflozin **as monotherapy** is recommended as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:
 - a dipeptidyl peptidase 4 (DPP 4) inhibitor would otherwise be prescribed* **and**
 - a sulfonylurea or pioglitazone is not appropriate
- > Ertugliflozin **in a dual therapy regimen in combination with metformin** is recommended as an option for treating type 2 diabetes, only if:
 - a sulfonylurea is contraindicated or not tolerated **or**
 - the person is at significant risk of hypoglycaemia or its consequences
- > If patients and their clinicians consider ertugliflozin to be one of a range of suitable treatments including canagliflozin, dapagliflozin and empagliflozin, the least expensive should be chosen.

*See NICE Guideline 28 (last updated May 2017), Type 2 diabetes in adults: management [Algorithm for blood glucose lowering therapy in adults with type 2 diabetes](#) for where a DPP-4 inhibitor would otherwise be prescribed.

NB: the effectiveness of SGLT-2 inhibitors is dependent on adequate renal function; see the “Implementation Notes” for further details.

[Ertugliflozin for use as part of a triple therapy](#) regimen is currently not recommended for use within the Pan Mersey health economy. A separate NICE TA for this indication is expected to be published in June 2019.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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<p>Effectiveness</p> <p>Ertugliflozin is the fourth sodium-glucose cotransporter-2 (SGLT-2) inhibitor available in the UK. It lowers blood glucose by blocking the reabsorption of glucose in the kidneys and promoting excretion of excess glucose in the urine.</p> <p>NICE TA572 concluded that indirect comparisons demonstrate that ertugliflozin has similar overall health benefits to canagliflozin, dapagliflozin and empagliflozin. The acquisition cost of ertugliflozin is lower than the acquisition costs of these other drugs. Ertugliflozin is therefore recommended as an option for treating type 2 diabetes as monotherapy or with metformin in line with the previous recommendations for SGLT-2 inhibitors.^[1]</p>	<p>Safety^[2]</p> <p>Contraindications: hypersensitivity to the active ingredient or any of the excipients, type 1 diabetes, treatment of diabetic ketoacidosis.</p> <p>Ertugliflozin causes an osmotic diuresis, which may lead to intravascular volume contraction causing symptomatic hypotension, particularly in impaired renal function, elderly, patients on diuretics or on anti-hypertensive therapy with a history of hypotension. Before initiation, volume status should be assessed and corrected if indicated.</p> <p>In case of conditions that may lead to fluid loss (e.g. GI illness), careful monitoring of volume status and electrolytes is recommended. Temporary interruption of ertugliflozin treatment should be considered until the fluid loss is corrected.</p> <p>Urinary glucose excretion may be associated with an increased risk of urinary tract infections.</p> <p>Increased risk of genital mycotic infections.</p> <p>Limited experience in heart failure NYHA class I - II, none in NYHA class III – IV.</p> <p>The MHRA issued an updated alert on increased risk of lower extremity amputations with another SGLT-2 inhibitor. It is unknown if this is a class effect.</p> <p>Drug Safety Update (Feb 19) advised of post-marketing reports of Fournier's gangrene associated with SGLT-2 inhibitors. Consult the SPC for full information.</p>
<p>Cost^[3] annual cost per patient</p> <p>Canagliflozin: £477 Dapagliflozin: £477 Empagliflozin: £477 Ertugliflozin: £383</p>	<p>Patient factors^[2]</p> <p>Should not be initiated in patients with an eGFR <60 ml/min/1.73 m². Discontinue when eGFR is persistently <45 ml/min/1.73 m².</p> <p>Should not be used in patients with severe renal impairment, with end-stage renal disease (ESRD), or receiving dialysis, as it is not expected to be effective in these patients</p> <p>Hepatic impairment: Mild/moderate, no dosage adjustment. Severe, not recommended.</p> <p>Not recommended in patients ≥ 75 years of age, due to limited experience.</p>

Prescribing information^[2]

The recommended starting dose of ertugliflozin is 5 mg once daily. In patients tolerating ertugliflozin 5 mg once daily, the dose can be increased to 15 mg once daily if additional glycaemic control is needed. Ertugliflozin should be taken orally once daily in the morning, with or without food. In case of swallowing difficulties, the tablet could be broken or crushed as it is an immediate-release dosage form.

When ertugliflozin is used in combination with an insulin secretagogue, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycaemia.

Implementation notes

Renal function should be monitored prior to initiation of ertugliflozin and at least yearly thereafter. Additional monitoring is recommended prior to initiation of concomitant medicines that may reduce renal function and periodically thereafter.

Ertugliflozin should not be initiated in patients with an eGFR <60 ml/min/1.73m² and should be discontinued if eGFR persistently < 45 ml/min/1.73m².^[2]

Supporting information

References

1. National Institute for Health and Care Excellence. [NICE TA572](#): Ertugliflozin as monotherapy and in dual therapy for treating type 2 diabetes, 27 March 2019. Accessed online 27 March 2019
2. Merck, Sharp and Dohme Limited. Summary of Product Characteristics: [Steglatro 5 mg and 15 mg film-coated tablets](#), 28 August 2018. Accessed online 05 March 2019.
3. NHSBA Dictionary of Medicine and Devices ([dm+d Browser](#)). Accessed 05 March 2019.