The Shrewsbury and Telford Hospital NHS
NHS Trust

NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

Prescribing information for dapagliflozin (Forxiga) for treating chronic heart failure with reduced ejection fraction

Licensed Indication

Dapagliflozin (Forxiga) is indicated in adult patients for treatment of chronic heart failure with reduced ejection fraction.

NICE[1] support the use of dapagliflozin (Forxiga) under the following criteria:
It is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care with:

- Angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor blockers (ARBs), with beta blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or
- Sacubitril valsartan with beta blockers, and, if tolerated, MRAs

Dosage and administration[2]

Dapagliflozin (Forxiga) is administered orally. The recommended dose is 10mg once daily. Tablets are to be swallowed whole at any time of day with or without food.

There is no dose adjustment required for patients with renal impairment. Treatment should not be initiated in patients with severe renal impairment (GR <30 ml/min)[2]

Patients with Type-2 diabetes mellitus

Note Dapagliflozin is not recommended for treatment of heart failure in patients with Type-1 diabetes mellitus[2]

Patients taking insulin or insulin secretagogue for type-2 diabetes may require their doses to be reduced as Dapagliflozin can increase the risk of hypoglycaemia. The patient's specialist diabetes team should be contacted for advice.

In patients treated with dapagliflozin (Forxiga) for both heart failure and type 2 diabetes mellitus, additional glucose-lowering treatment should be considered if GFR is persistently between 30 - 45 ml/min.[2] Efficacy of dapagliflozin in lowering blood glucose levels is reduced if GFR is <45ml/min.

Specialist responsibilities

- Discuss the benefits and side effects of treatment with the patient.
- Initiate treatment with dapagliflozin (Forxiga).
- Identify patients with diabetes mellitus also taking other glucose lowering therapy and refer to their diabetes specialist for advice on lowering doses of concomitant medication if appropriate.
- Check renal function and any contra-indications to dapagliflozin (Forxiga)
- Communicate to the GP that treatment has been initiated, the follow up arrangements and when to refer back.
- Communicate promptly with the GP when treatment is changed.
- Review patient annually, and give advice on stopping treatment.
- Have a mechanism in place to receive referral of a patient from the GP in the event of rare or severe side-effects.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support
- Ensure the patient can recognise the signs of hypoglycaemia and how to treat it.
- Inform the patient to stop taking dapagliflozin if they are acutely unwell and have reduced oral intake. Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Primary Care responsibilities

- Prescribe the dapagliflozin (Forxiga) from the agreed date.
- Monitor renal function annually (more frequently if patient at risk) and report significant findings to the specialist.

- For patients with Type-2 diabetes mellitus, monitor their blood glucose and titrate other glucose lowering medication in line with advice from diabetes specialists.
- Report to and seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
- Refer back to specialist if the patient's condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

Monitoring

Renal function should be checked at least annually. For patients with type-2 diabetes mellitus, increase frequency of blood glucose monitoring and continue to monitor renal function and HbA1c.

Contra-indications, Special warnings/precautions & adverse effects

Contra-indications:
Hypersensitivity to the active substance or to any of the excipients

Not suitable to treat heart failure in patients with Type 1 diabetes

Special warnings/precautions:
Experience with dapagliflozin in NYHA class IV is limited.

Diabetic ketoacidosis may occur in patients taking dapagliflozin. Patients should be advised to temporarily withhold dapagliflozin if they are unwell, have reduced oral intake, or prior to surgery to reduce the risk of developing ketoacidosis.

Fournier's gangrene has been reported in both male and female patients taking dapagliflozin. Patients should be advised to seek medical attention if they experience pain, tenderness, redness or swelling of the genital or perineal area.

Caution should be exercised in patients for whom a dapagliflozin-induced drop in blood pressure could pose a risk, such as patients on anti-hypertensive therapy with a history of hypotension or elderly patients. Risk of hypotension is highest in type-2 diabetics with poor glycaemic control.

Adverse Effects
Hypoglycaemia (when used with sulfonylureas or insulin), vulvovaginitis, balanitis and related genital infections, Urinary tract infection, dizziness, rash, back pain, dysuria, polyuria, Haematocrit increased, creatinine renal clearance decreased during initial treatment, dyslipidaemia[2]

Drug Interactions

Diuretics, insulin and insulin secretagogues,

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics or the British National Formulary.

[1] NICE TA679 February 2021
[2] Summary of Product Characteristics https://www.medicines.org.uk/emc/product/7607/smpc Accessed 25/04/2021