

# Information for Primary Care – Dapagliflozin for the treatment of heart failure

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Approved by	South Tyneside and Sunderland Area Prescribing Committee and relevant groups / committees within stakeholder organisations
Current Version	1
Published on	October 2021
Review date	October 2024
Version control	

This information is intended for use in primary care

Information for Primary Care – Dapagliflozin for the treatment of heart failure.

<b>RAG Status – Green +</b>
<b>Background/Summary Information</b>
<p>Dapagliflozin (Forxiga®) is a Sodium Glucose Co-Transporter<sub>2</sub> Inhibitor (SGLT<sub>2</sub>) indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction with or without diabetes.</p> <p>Treatment of heart failure with dapagliflozin should be initiated on advice of a heart failure specialist.</p>
<b>Related NICE guidance</b>
<p>NICE (TA 679) <a href="http://www.nice.org.uk/guidance/ta679">www.nice.org.uk/guidance/ta679</a></p> <ul style="list-style-type: none"> <li>• Dapagliflozin 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:             <ul style="list-style-type: none"> <li>• angiotensin-converting enzyme (ACE) inhibitors or angiotensin 2 receptor blockers (ARBs), with beta blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or</li> <li>• sacubitril valsartan, with beta blockers, and, if tolerated, MRAs.</li> </ul> </li> </ul>
<p>See manufacturers SPC for full prescribing information <a href="http://www.medicines.org.uk/emc/product/7607/smpc">www.medicines.org.uk/emc/product/7607/smpc</a></p>
<b>Licensed indications</b>
<p><b><u>Heart failure</u></b></p> <p><b>Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.</b></p> <p><u>Type 2 diabetes mellitus</u></p> <p>Forxiga is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise</p> <ul style="list-style-type: none"> <li>- as monotherapy when metformin is considered inappropriate due to intolerance.</li> <li>- in addition to other medicinal products for the treatment of type 2 diabetes.</li> </ul> <p>For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.</p> <p><u>Chronic kidney disease</u></p> <p>Forxiga is indicated in adults for the treatment of chronic kidney disease.</p>

**Dosage and administration**

Usual dose: Dapagliflozin 10mg daily

Key Points for safe use:

For **non-diabetic patients** Dapagliflozin can be added to standard therapy without the need to change existing therapy. Fluid status should be reviewed post initiation.

For **diabetic patients with and eGFR >45ml/min** modification of diabetic therapy may be required.\*

For **diabetic patients with and eGFR <45ml/min** NO modification of diabetic therapy is necessary.

*\*Modification of diabetic therapy may be completed by the specialist initiating dapagliflozin if competent, if this is felt outside their competence then the patient will be referred back to the clinician currently providing diabetes care i.e. either GP/practice nurse or where already known, to secondary care.*

GP responsibilities:

- The GP will provide prescriptions for the patient post initiation. **(Please note: where appropriate the initiating prescriber should provide the first prescription however, there may be cases where the GP is asked to do so i.e. patients using monitored dosing systems or GP advice is sought to determine changes of diabetic therapy).**
- The GP will be responsible for annual monitoring.

Specialist responsibilities:

- The heart failure specialist initiating dapagliflozin are responsible for, ensuring the patient understands the changes to their medicines and has received adequate counselling of the medication, side effects, sick day rules etc.
- The initiating specialist will be responsible to arranging 2-4 week blood monitoring. This should take place as part of a heart failure review post treatment initiation however, there may be times when alternate arrangements are felt necessary i.e. house bound patients.
- The heart failure specialist team are happy to provide general advice regarding Dapagliflozin, and can be contacted via the hospital switch board (0191 5656256). Patient specific queries should be dealt with via the initiating prescriber.

**Contraindications**

Dapagliflozin is contra indicated in the following:

- Type 1 Diabetes (known or suspected, including secondary diabetes due to pancreatitis)
- History of diabetic ketoacidosis (DKA)
- History of allergic reaction to Dapagliflozin
- Severe renal impairment eGFR less than 15 ml/min/1.73m<sup>2</sup>, ESRD, or patients on dialysis
- Pregnancy or breastfeeding

<b>Cautions</b>
<ul style="list-style-type: none"> <li>• Peripheral Arterial Disease with active diabetic foot ulcer or previous minor amputation</li> <li>• History or recurrent urinary tract sepsis, recurrent candida, or known kidney stones</li> <li>• Severe hepatic impairment (recommended dose 5mg od)</li> </ul>
<b>Side effects</b>
<p>The most common side effects include:</p> <ul style="list-style-type: none"> <li>• Hypoglycaemia (when used with SU or insulin)</li> <li>• Vulvovaginitis, balanitis and related genital infections</li> <li>• Urinary tract infection</li> <li>• Dizziness</li> <li>• Rash</li> <li>• Back pain</li> <li>• Dysuria</li> <li>• Polyuria</li> <li>• Haematocrit increased</li> <li>• Creatinine renal clearance decreased during initial treatment</li> <li>• Dyslipidaemia</li> </ul>
<b>Drug Interactions</b>
Dapagliflozin has no severe interactions listed. The full list of interacting medication can be found in the SPC.
<b>Monitoring</b>
<p>Volume status in those at risk of volume depletion. Ketone monitoring in those at risk of DKA. Renal function before treatment, after 2-4 weeks and then at least annually. Ongoing monitoring should be done by primary care unless otherwise advised by the initiating specialist.</p>
<b>Cost</b> £36.59 for 28 days