

## Product Update

dapagliflozin plus metformin 5mg/850mg and 5mg/1000mg film-coated  
tablets (Xigduo<sup>®</sup>) (No: 983/14)

AstraZeneca

04 July 2014

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

**ADVICE:** following an abbreviated submission

**dapagliflozin plus metformin (Xigduo<sup>®</sup>)** is accepted for restricted use within NHS Scotland.

**Indication under review:** in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients inadequately controlled on their maximally tolerated dose of metformin alone;
- in combination with other glucose-lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products;
- in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.

**SMC restriction:** to use in patients for whom a combination of dapagliflozin and metformin is an appropriate choice of therapy i.e.

- when metformin alone does not provide adequate glycaemic control and a sulphonylurea is inappropriate.
- in combination with insulin, when insulin and metformin does not provide adequate control.
- in combination with a sulphonylurea, when a sulphonylurea and metformin does not provide adequate control.

Dapagliflozin in combination with metformin has been shown to be bioequivalent to dapagliflozin and metformin administered separately and dapagliflozin administered twice daily has been shown to provide similar exposure to the equivalent dose administered once daily.

**Advice context:**

*No part of this advice may be used without the whole of the advice being quoted in full.*

*This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.*

This assessment is based on data submitted by the applicant company up to and including 15 May 2014.

**Chairman  
Scottish Medicines Consortium**