

Product Update:

saxagliptin 5mg / dapagliflozin 10mg film-coated tablets (Qtern®)

SMC No (1255/17)

AstraZeneca

9 June 2017

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

saxagliptin/dapagliflozin 5mg/10mg (Qtern®) is accepted for restricted use within NHS Scotland.

Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® do not provide adequate glycaemic control,
- when already being treated with the free combination of dapagliflozin and saxagliptin

SMC restriction: for use in combination with metformin when the use of a sulphonylurea is inappropriate.

In patients for whom this combination is appropriate, saxagliptin/dapagliflozin (Qtern®) offers a single tablet at a lower cost per dose compared with the individual components.

The marketing authorisation for saxagliptin currently specifies the medicines that may be given concomitantly but is to be amended to 'use in combination with other diabetes medicines'. It is anticipated that this licence change will be outwith SMC remit.

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 2017.

**Chairman
Scottish Medicines Consortium**