

Product Update

saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets
(Komboglyze®) (No: 870/13)

Bristol Myers Squibb / AstraZeneca

10 May 2013

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

saxagliptan plus metformin is accepted for restricted use within NHS Scotland.

Indication under review: adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets.

SMC restriction: use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate.

Saxagliptin represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of HbA1c, is comparable to another dipeptidyl peptidase-4 inhibitor. It appears to have minimal effect on body weight.

Saxagliptin/metformin is also licensed for use in combination with insulin for the treatment of type 2 diabetes. The manufacturer's submission related only to the use of saxagliptin and metformin in combination therefore SMC cannot recommend the use of saxagliptin/metformin in combination with insulin.

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 14 March 2013.

**Chairman
Scottish Medicines Consortium**