Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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Product Update

olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide 20mg/5mg/12.5mg, 40mg/5mg/12.5mg, 40mg/10mg/12.5mg, 40mg/5mg/25mg, 40mg/10mg/25 mg film-coated tablets (Sevikar HCT®) (No: 706/11)

Daiichi Sankyo UK Ltd

06 May 2011 *(Issued 09 September 2011)*

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

olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) is accepted for use within NHS Scotland.

Indication under review: as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlodipine).

In a phase III randomised four-arm study of patients with moderate to severe hypertension Sevikar HCT was superior to three dual combination therapies for the the primary endpoint, change in diastolic pressure.

In patients for whom concomitant use of these medicines is appropriate it allows administration of a single tablet at a lower or modestly increased cost (depending on dose) compared to another dual combination product plus single component. Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated. These fixed dose combinations are among many options for the treatment of hypertension, many of which are less expensive.

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 ***08 April 2011.***

Chairman
Scottish Medicines Consortium