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

Product Update:

sildenafil citrate 0.8mg/mL solution for injection (Revatio®) (No: 688/11)

Pfizer UK

04 February 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

sildenafil citrate 0.8mg/mL injection (Revatio®) is accepted for restricted use within NHS Scotland.

Indication under review: for the treatment of patients with pulmonary arterial hypertension who are currently prescribed oral sildenafil and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable.

SMC restriction: restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service.

Oral sildenafil is indicated for treatment of patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.

SMC has previously accepted oral sildenafil in this orphan indication. The intravenous formulation is significantly more expensive than the oral preparation but it is intended only for short-term use (the estimated average duration of intravenous treatment is three days).

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 09 December 2010.

Chairman, Scottish Medicines Consortium

Published 07 March 2011