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

esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®) (No:639/10)

AstraZeneca UK Ltd

06 August 2010

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

esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®): is accepted for restricted use within NHS Scotland.

Indication under review: primarily indicated for treatment of gastro-oesophageal reflux disease in children 1 to 11 years old.
Gastro-oesophageal reflux disease (GORD)

- Treatment of endoscopically proven erosive reflux oesophagitis
- Symptomatic treatment of gastro-oesophageal reflux disease

Oral suspension may also be used by patients having difficulty swallowing dispersed esomeprazole gastro-resistant tablets.

Restricted Advice: the use of esomeprazole for this indication and age group should be restricted to patients in whom licensed doses of a generic proton pump inhibitor have been ineffective.

The gastro-resistant granules for oral solution have demonstrated bioequivalence to the tablet and capsule formulations. Doses of 10mg esomeprazole in children aged 1 to 11 resulted in the same exposure to drug as seen with the 20mg dose in adolescents and adults. There is no evidence of comparative efficacy in this population.

The Scottish Medicines Consortium has previously accepted this product for use in patients in the 12-17 years age group, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease.

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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 16 June 2010.

Chairman
Scottish Medicines Consortium