

mesalazine modified release tablet 800 mg (Asacol)

Procter and Gamble Pharmaceuticals UK Ltd

(No: 222/05)

Moderate acute exacerbations of ulcerative colitis

Product Update

9 December 2005 (*Issued January 2008*)

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

Mesalazine 800 mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the treatment of moderate acute exacerbations of ulcerative colitis up to a maximum dose of 4.8 g daily.

The maximum recommended dose has been increased from 2.4 g daily, and at the revised dose, the 800 mg strength allows halving of the pill burden compared with the 400 mg formulation. There will be a pro-rata increase in cost associated with the new maximum dose but no extra costs arise from the change in formulation.

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 9 November 2007.

Chairman, Scottish Medicines Consortium