

## Product Update:

Budesonide 9mg gastro-resistant granules (Budenofalk®)

(No 831/12)

Dr Falk Pharma UK Ltd

07 December 2012

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

**Budesonide 9mg gastro-resistant granules (Budenofalk®)** is accepted for use within NHS Scotland.

**Indication under review:** induction of remission in patients with active collagenous colitis.

Budesonide gastro-resistant granules provides a once daily alternative to budesonide gastro-resistant 3mg capsules (which are given three times daily) at no additional cost. The granules may have advantages for patients who have difficulty swallowing.

### **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 October 2012.*

**Chairman  
Scottish Medicines Consortium**