

**bosentan 62.5mg, 125mg film coated tablets (Tracleer)
(No. 485/08)**

Actelion Pharmaceuticals UK

Statement of Advice

09 May 2008

ADVICE: in the absence of a submission from the holder of the marketing authorisation.

bosentan (Tracleer) is not recommended for use within NHSScotland to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

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. 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.

**Chairman,
Scottish Medicines Consortium**