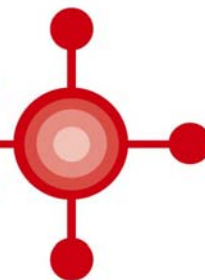


All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



Bosentan (Tracleer[®])

Actelion Pharmaceuticals UK Ltd

April 2009

Appraisal notice to NHS Wales

Bosentan (Tracleer[®]) has not been endorsed for use within NHS Wales for the treatment of digital ulceration in severe Raynauds Disease.

The holder of the marketing authorisation is not in a position to progress a submission to AWMSG for the appraisal of bosentan (Tracleer[®]) for the above indication. As a result, AWMSG cannot provide advice to the Minister for Health and Social Services.

AWMSG takes into account the NICE future work programme when considering whether a product will be appraised. AWMSG does not normally consider appraising a product if NICE intends to publish their final appraisal of the same product within a 18 month period from receipt of Form B. i.e. approx 12 months from the projected AWMSG appraisal date. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

This notice is provided for information to NHS Wales. In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

**Chairman
All Wales Medicines Strategy Group**

April 2009