



Final Appraisal Recommendation

Advice No: 4215 – December 2015

Macitentan (Opsumit®) 10 mg film-coated tablets

Submission by Actelion Pharmaceuticals UK Ltd

Recommendation of AWMSG

Macitentan (Opsumit®) is recommended as an option for use within NHS Wales as monotherapy or in combination for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Additional note(s):

- The use of macitentan (Opsumit®) should be directed by a physician experienced in the treatment of PAH at one of the designated pulmonary hypertension services across the UK.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 711), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Actelion Pharmaceuticals UK Ltd
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