



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE  
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION\***  
**for**  
**TRACLEER**

International Nonproprietary Name (INN): *bosentan*

On 26 June 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion\*\* to recommend the variation to the terms of the marketing authorisation for the medicinal product Tracleer. The Marketing Authorisation Holder for this medicinal product is Actelion Registration Ltd.

The CHMP adopted *a new indication* as follows:

“Some improvements have also been shown in patients with PAH WHO functional class II (see section 5.1).”

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Tracleer will be as follows\*\*\*:

“Treatment of pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with WHO functional class III.

Efficacy has been shown in:

- Primary (idiopathic and familial) PAH
- PAH secondary to scleroderma without significant interstitial pulmonary disease
- PAH associated with congenital systemic-to-pulmonary shunts and Eisenmenger’s physiology

**Some improvements have also been shown in patients with PAH WHO functional class II (see section 5.1.)**

Tracleer is also indicated to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease (see section 5.1).”

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\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

\*\* Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

\*\*\* The text in bold represents the new or the amended indication.