



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/52026/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Opsumit

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: MACITENTAN

Procedure No. EMEA/H/C/002697/PSUV/0003

Period covered by the PSUR: 20 December 2013 – 17 April 2014



## **Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR for Opsumit, the scientific conclusions of PRAC are as follows:

A signal of hypersensitivity has been assessed during this PSUR for which a total of 45 serious cases from clinical trials and 57 cases from postmarketing sources (9 serious cases and 48 non-serious cases) were identified. From postmarketing data 8 cases and from clinical trials two cases supported a possible causal relationship. Most of PTs reported are related to skin reactions (no cases of toxic epidermal necrolysis or Stevens- Johnson syndrome were reported). Hypersensitivity reactions are a known class effect of endothelin receptor antagonists, and were reported in the post-marketing setting with other products of this class.

Overall, the PRAC considers that in the light of all safety data provided, a possible causal relationship between macitentan and hypersensitivity reactions is supported and therefore hypersensitivity reactions should be included in the PI of macitentan.

Therefore, in view of available data regarding hypersensitivity, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

## **Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for Opsumit, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance MACITENTAN is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.