



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

## New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 6-9 June 2016 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

### **Riociguat – Increased mortality and serious adverse events (SAEs) in patients with pulmonary hypertension (PH) associated with idiopathic interstitial pneumonias (IIP) in a single clinical trial (EPITT no 18681)**

#### Summary of product characteristics

Section 4.3 – Contraindications

- Patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) (see Section 5.1)

Section 5.1 - Pharmacodynamic properties

Clinical efficacy and safety

Patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP)

A randomised, double blind, placebo-controlled phase II study (RISE-IIP) to evaluate the efficacy and safety of riociguat in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) was terminated early. Interim results showed an increased risk of mortality and serious adverse events in subjects receiving riociguat compared to those receiving



placebo. The available data do not indicate a clinically significant benefit from riociguat treatment in these patients.

Riociguat is therefore contraindicated in patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (see section 4.3).

### **Package leaflet**

Section 2 - What you need to know before you take Adempas

Do NOT take Adempas:

- If you have increased pressure in your pulmonary circulation associated with scarring of the lungs, of unknown cause (idiopathic pulmonary pneumonia).