



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Riociguat

August 3, 2017

Non-proprietary name

Riociguat

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

In a multiregional study in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias, increased incidences of serious adverse events or fatal outcomes were observed in patients receiving this drug compared with patients receiving placebo. For patients with pulmonary arterial hypertension associated with interstitial pneumopathy, the risks and benefits should be considered in advance by means such as consulting with a physician versed in the treatment of interstitial lung disease and a careful decision on administration should be made.