

Pirespa[®] 200mg Tablet Launched
Idiopathic Pulmonary Fibrosis Treatment

Osaka, December 12, 2008 -- Shionogi & Co., Ltd. (Head Office: Osaka; President: Isao Teshirogi) today announced that it launched Pirespa[®] 200mg Tablet (generic name: Pirfenidone), an Idiopathic Pulmonary Fibrosis treatment, on December 12.

Pirespa[®] has a fibrosis inhibiting effect and it was licensed from U.S.-based Marnac, Inc. and KDL, Inc., Tokyo. Shionogi had developed it in Japan and received marketing and manufacturing approval on October 16 for the first time in the world. Inhibiting fibrosis itself is a new mechanism of action and clinical trials showed it preserved vital capacity as well as it inhibited decrease of progression-free survival. Based on the results of the clinical studies, it is expected that Pirespa[®] slows the progression of Idiopathic Pulmonary Fibrosis.

We will prioritize securing the safety of patients who take Pirespa[®] and will do our utmost to make a larger contribution to the treatment for Idiopathic Pulmonary Fibrosis by making every effort to collect and provide information on the proper use to get Pirespa[®] properly prescribed.

We conduct post-marketing surveillance on all the patients taking Pirespa[®] during a specific period of time after launch. As the surveillance starts, we

beforehand request cooperation and proper use of the drug as well as agreements of the survey from medical institutions.

For Reference:

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is a medical condition of unknown etiology with poor prognosis in which progressive fibrosis of the alveolar walls produces irreversible “honeycomb lung”*. In general, restrictive impairment (reduction of vital capacity (VC) and total lung capacity (TLC)) is evident. As the symptom (fibrosis of the alveolar walls) progresses, gas exchange in the lungs (exchange of oxygen and carbon dioxide) becomes difficult. In some cases, oxygen therapy becomes necessary. Because of its severity, IPF is designated as a “specified disease” (in other words, an intractable disorder).

*Honeycomb lung: A high-resolution CT scan of the lung yields a honeycomb pattern.

Product Overview

Product Name:	Pirespa [®] 200mg Tablet
Generic Name:	Pirfenidone
Effect:	Idiopathic Pulmonary Fibrosis
Form and Content:	Film-coated tablet containing 200mg of Pirfenidone in one tablet
Dosage and Administration:	Generally in adults, one 200mg tablet as a primary dosage is administered orally three times daily (600mg in a day) after meal. The dosage is increased by 200mg increments per admin up to 600mg per admin (1800mg in a day), examining condition of the patient. The dosage should be adjusted according to the patient’s condition.
Approval date:	October 16, 2008

NHI drug price

listing:

December 12, 2008

Price:

676.40 yen per tablet

For further information:

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