FOR USE IN IRELAND

SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN
(Pirfenidone)

Before initiating Pirfenidone, and in addition to reading the Summary of Product Characteristics, please check each of the following:

Drug-induced Liver Injury

Prior to initiation of treatment:

☐ The patient does not have severe hepatic impairment or end stage liver disease. Pirfenidone is contraindicated in patients with severe hepatic impairment or end stage liver disease

☐ Liver function tests have been performed prior to initiation of treatment with Pirfenidone

☐ I am aware that elevations of serum transaminases can occur during treatment with Pirfenidone

☐ The patient is informed that serious liver injury may occur and that he/she should contact their prescribing physician or regular physician immediately for clinical evaluation and liver function tests if symptoms of liver injury including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice (as described in the patient information leaflet) occur

During treatment:

☐ Liver function tests will be performed monthly in the first six months of treatment

☐ Liver function tests will be performed every three months thereafter during treatment

☐ Patients who develop liver enzyme elevations will be closely monitored and the dose of Pirfenidone will be adjusted or treatment will be permanently discontinued if necessary (please refer to the Summary of Product Characteristics for recommendations)

☐ Prompt clinical evaluation and liver function tests will be performed if a patient develops symptoms or signs of liver injury (please refer to the Summary of Product Characteristics for recommendations)

Photosensitivity

☐ The patient is informed that Pirfenidone is known to be associated with photosensitivity reactions and that preventive measures have to be taken

☐ The patient is advised to avoid or reduce exposure to direct sunlight (including sunlamps)

☐ The patient is instructed to use a sunblock daily, to wear clothing that protects against sun exposure, and to avoid other medications known to cause photosensitivity

☐ The patient is informed that he/she should report to the prescribing physician or regular physician if any new and significant skin rash occurs

Reporting of adverse events

Healthcare professionals should report any adverse events suspected to be associated with the use of pirfenidone according to the national reporting requirements. If you are aware of any suspected adverse reactions associated with the use of pirfenidone, including clinically significant photosensitivity reactions and skin rashes, drug-induced liver injury, clinically significant abnormal liver function tests and any other clinically significant adverse drug reactions, please report such information as follows:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions (see details below).

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:

HPRA Pharmacovigilance
Website: www.hpra.ie

or

axunio Pharma GmbH
Van-der-Smissen Str. 1
22767 Hamburg
Germany
by mail or email to medinfo@axunio.eu.

Further information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Pirfenidone axunio' or 'pirfenidone' in the search box and click on the 'EdM' link).

Alternatively, if you would like hard copies, please contact
axunio Pharma GmbH
Van-der-Smissen Str. 1
22767 Hamburg
Germany
by mail or email to medinfo@axunio.eu.