SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

Esbriet (pirfenidone)

Before initiating Esbriet (pirfenidone), and in addition to reading the Product Insert, 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. Esbriet 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 Esbriet.
- ☐ I am aware that elevations of serum transaminases can occur during treatment with Esbriet.
- ☐ 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 Esbriet will be adjusted or treatment will be permanently discontinued if necessary (please refer to the Product Insert 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 Product Insert for recommendations).

Photosensitivity

- ☐ The patient is informed that Esbriet 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 Esbriet according to national reporting requirements.

If you are aware of any suspected adverse reactions associated with the use of Esbriet, including clinically significant photosensitivity reactions and skin rashes, drug-induced liver injury, clinically significant abnormal liver function tests and any other clinically significant ADRs, please report such information to Roche Hong Kong.

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Date of Preparation: Dec 2020