SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

Esbriet (pirfenidone)

This safety checklist contains the following key elements for the safe use of Esbriet (pirfenidone) as follows:

Liver function

- Esbriet is contraindicated in patients with severe hepatic impairment or end stage liver disease.
- Drug-Induced Liver Injury (DILI) in the form of transient and clinically silent elevations in transaminases, has been commonly reported in patients treated with Esbriet. In rare cases, these elevations were associated with concomitant bilirubin increases, and serious clinical consequences including isolated cases with fatal outcome have been reported post-marketing.
- There is a need to monitor liver function tests prior to initiation of treatment with Esbriet and at regular intervals thereafter.
- Close monitoring is required of any patients who develop liver enzyme elevation with appropriate dose adjustment or discontinuation.

Photosensitivity

- Patients should be informed that Esbriet is known to be associated with photosensitivity reactions and that preventative measures have to be taken.
- Patients are advised to avoid or reduce exposure to direct sunlight (including sunlamps).
- Patients should be instructed to use a sunblock daily, to wear clothing that protects against sun exposure, and to avoid other medications known to cause photosensitivity.

Before initiating Esbriet (pirfenidone), in addition to reading the SUMMARY OF PRODUCT CHARACTERISTICS , please check the following points:

Indication for use

- o I am satisfied that the patient has a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF).
- o I have started therapy and that the patient has been advised that therapy will be titrated according to the recommendations of the SUMMARY OF PRODUCT CHARACTERISTICS
- o I have advised the patient to take Esbriet (pirfenidone) with food and to avoid grapefruit and grapefruit juice while they are being treated with Esbriet.

<u>Key warnings: please check</u>

Before starting Esbriet I have checked whether

- o The patient is hypersensitive to pirfenidone.
- o The patient is not on medication which could potentially interact adversely with Esbriet
- o I have arranged for adequate monitoring for abnormal liver functions tests.

Drug-induced Liver Injury

<u>Prior to initiation of treatment:</u>

- o 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
- o Liver function tests have been performed prior to initiation of treatment with Esbriet
- o I am aware that elevations of serum transaminases can occur during treatment with Esbriet
- o 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

<u>During treatment:</u>

- o Liver function tests will be performed monthly in the first six months of treatment
- o Liver function tests will be performed every three months thereafter during treatment
- o 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 SmPC for recommendations)
- o Prompt clinical evaluation and liver function tests will be performed if a patient develops symptoms or signs of liver injury (please refer to the SmPC for recommendations)

Photosensitivity

- o The patient is informed that Esbriet is known to be associated with photosensitivity reactions and that preventive measures have to be taken
- o The patient is advised to avoid or reduce exposure to direct sunlight (including sunlamps)
- o 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
- o The patient is informed that he/she should report to the prescribing physician or regular physician if any new and significant skin rash occurs

Once Esbriet (pirfenidone) has been administered, I have asked the patient to contact me or their regular physician if they experience:

- o Any new and significant skin rash
- o If the skin or the whites of the eyes turn yellow of if they experience dark urine
- o Any worrying or alarming symptoms or signs which might be related to pirfenidone

I will refer to the SUMMARY OF PRODUCT CHARACTERISTICS for further information on safe use

I understand that I will report all serious adverse reactions, including clinically significant photosensitivity reactions and skin rashes, clinically significant abnormal liver function tests and any other clinically significant ADRs based on my judgment, in accordance with national reporting requirements to the address below:

Reporting of adverse events:

The National Pharmacovigilance and Drug Safety Centre (NPC)
Landline: 19999
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Website: https//:ade.sfda.gov.sa

Roche Products Saudi Arabia L.L.C.
Direct tel: +966122114618
Mobile: +966 5678 44 692
E-mail: Jeddah.drug_safety@roche.com
Local Safety Responsible: doha.samargandi@roche.com
www.roche.com

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

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