ADDITIONAL RISK MINIMISATION MEASURES (DETAILS OF SAFETY CHECKLIST)

Roche Products Saudi Arabia L.L.C

Dear Healthcare Professional

Esbriet® (pirfenidone**)**

Roche Products Saudi Arabia L.L.C wishes to inform you about relevant safety information concerning the use of Esbriet® (pirfenidone).

SUMMARY

Esbriet® (pirfenidone) is approved in Saudi Arabia for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF).

Please find attached the Safety Checklist for your reference which highlights some key warnings. You should always read the current version of the Patient information leaflet

INDICATION FOR USE

Esbriet® (pirfenidone) is authorised for the treatment IN ADULTS OF MILD TO MODERATE IDIOPATHIC PULMONARY FIBROSIS (IPF). This treatment should be used in adults only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of IPF.

We trust that the enclosed information will assist you in using Esbriet® to manage your patients appropriately.

We would like also to remind you of the importance of Healthcare Professionals to report suspected adverse reactions in accordance with your National Pharmacovigilance and drug safety Centre If you are aware of any suspected adverse reactions associated with the use of Esbriet®, please report such information to the following Address.

The National Pharmacovigilance and Drug Safety Centre (NPC)

Land Line: 19999.

Website: https://ade.sfda.gov.sa/

Email : npc.drug@sfda.gov.sa

Fax: +966112057662.

If you require further information about Esbriet® or have a question about any aspect of this letter, please contact:

Roche Products Saudi Arabia L.L.C.

Saudi Arabia P.O. Box 3683 Jeddah 23414

Direct Tel. +966 12211 4618

Mobile: +966 5678 44 692

Email: jeddah.drug_safety@roche.com

Local Safety Responsible: Hassan.linjawi@roche.com

www.roche.com

Please take time to read the Summary of Product Characteristics (SPC) for Esbriet®, which is enclosed.

Thank you very much for your time and attention.

Yours faithfully,

Local Safety Responsible

Hassan Linjawi

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.
- Elevations of serum transaminases can occur during treatment with Esbriet®.
- 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 Summary of Product Characteristics (SPC), please check the following points:

Indication for use

- I am satisfied that the patient is an adult with a diagnosis of the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF).

- 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 (SPC).
- I have advised the patient to take Esbriet® with food. And avoid grapefruit juice At the same time.

Key warnings: please check

Before starting Esbriet® I have checked whether: -

- The patient is hypersensitive to pirfenidone.
- The patient may have underlying hepatic disease.
- I have arranged for adequate monitoring for abnormal liver functions tests.
- I have advised the patient to avoid the sun and all sources of U.V. light, and what other measures can be taken such as taking extra care during the summer months.

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

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

I will refer to the Approved Summary of Product Characteristics (SPC) 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.

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