

SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

Esbriet®▼ (pirfenidone) 267 mg capsules

This safety checklist contains key elements to follow when prescribing Esbriet® 267mg capsules:

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. Appropriate dose adjustment or discontinuation may be required.

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 267mg capsules (pirfenidone), in addition to reading the Summary of Product Characteristics (SmPC), please check the following points:

Indication for use

- I am satisfied that the patient is an adult with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF).
- I have started therapy at one 267 mg capsule three times a day and that the patient has been advised that therapy will be titrated according to the recommendations of the SmPC.
- I have advised the patient to take the capsules with food and to avoid grapefruit juice while they are being treated with Esbriet.

Key warnings: please check

Before starting Esbriet I have:

- Checked whether the patient is hypersensitive to pirfenidone.
- Checked whether the patient is on medication which could potentially interact adversely with Esbriet.
- Checked whether the patient has underlying hepatic disease.
- Arranged for adequate monitoring for abnormal liver functions tests.
- Advised the patient to avoid the sun and all sources of U.V. light, to wear clothing that protects against sun exposure and what other measures can be taken such as taking extra care during the summer months.

Once Esbriet® 267mg capsules have been administered, I have asked the patient to contact me or their regular physician if they experience:

- Any new and significant skin rash or blistering
- Evidence of jaundice
- Any worrying or alarming symptoms or signs

I will refer to the Summary of Product Characteristics for further information on use of Esbriet.

I understand that I will report all adverse reactions in accordance with the national reporting requirements to the address below.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting forms and information can be found www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing Welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.