Safety checklist for prescribing physician Esbriet® (pirfenidone)

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

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 (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 267 mg three times a day and the patient has been advised that therapy will be titrated according to the recommendations of the SmPC.

☐ I have advised the patient to take Esbriet 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.

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Once Esbriet® has 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.

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or 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 events or 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:
The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700
Fax: 00 353 (0)1 4690793
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions should be reported to:
Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal

Further Information

For additional copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material or alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone [00 353 (0)1 4690700], fax [00 353 (0)1 4690793] or email [ireland.drug_surveillance_centre@roche.com].

For further information about this product, please contact Medical Information at Roche Products (Ireland) Limited by telephone [00 353 (0)1 4690700], fax [00 353 (0)1 4690793] or email [Ireland.druginfo@roche.com].

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

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