FOR USE IN MALTA

Safety Checklist for Prescribing Physician

Esbriet® (pirfenidone)

Before initiating Esbriet® (pirfenidone) and in addition to reading the Summary of Product Characteristics (SmPC), 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 Summary of Product Characteristics 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 Summary of Product Characteristics 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.

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.ema.europa.eu and www.medicines.ie before prescribing this medicine.

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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 as follows:

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

Alternatively, suspected adverse reactions or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:
http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

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

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

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