Safety Checklist for Prescribing Physician Pirfenidone Clonmel (pirfenidone)

Before initiating Pirfenidone Clonmel (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. Pirfenidone Clonmel 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 Pirfenidone Clonmel
I am aware that elevations of serum transaminases can occur during treatment with Pirfenidone Clonmel
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 Pirfenidone Clonmel 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 Pirfenidone Clonmel 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.

Reporting of adverse events:

Healthcare professionals should report any adverse events suspected to be associated with the use of Pirfenidone Clonmel according to national reporting requirements. If you are aware of any suspected adverse reactions associated with the use of Pirfenidone Clonmel, 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:

Clonmel Healthcare Ltd. Pharmacovigilance, Waterford Road, Clonmel, Co. Tipperary.
Email: medicalinformation@clonmel-health.ie
Telephone: (052) 6177777
Fax: (052) 6177791

Alternatively, suspected adverse reactions should be reported to:
Malta Medicines Authority
Website: www.medicinesauthority.gov.mt/adrportal.

Further Information

For electronic copies of this risk minimisation material, refer to https://medicinesauthority.gov.mt/rmm

Alternatively, if you would like hard copies of this risk minimisation material or further information about this medicine, please contact please contact medicalinformation@clonmel-health.ie or by telephone 052 6177777. Or the local representative Pharma.mt at regulatory@pharmamt.com or by telephone +356 21337008.

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