SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

Pirfenidone Accord 267 mg film-coated tablets
Pirfenidone Accord 801 mg film-coated tablets
(Pirfenidone)

This safety checklist contains key elements to follow when prescribing Pirfenidone Accord:

Before initiating Pirfenidone Accord, 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 Accord 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 Accord
- ☐ I am aware that elevations of serum transaminases can occur during treatment with Pirfenidone Accord
- ☐ 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 Accord will be adjusted or treatment will be permanently discontinued if necessary (please refer to the SmPC 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 SmPC for recommendations)

Photosensitivity

- ☐ The patient is informed that Pirfenidone Accord 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

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Reporting of adverse events
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
If you are aware of any suspected adverse drug reactions (ADR) associated with the use of Pirfenidone Accord, 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 to:

Medical information at Accord Healthcare Ltd via:
Email: medinfo@accord-healthcare.com
Telephone: +44(0)1271385257.

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information
For electronic copies of this risk minimisation material, refer to www.hpra.ie (enter 'Pirfenidone Accord' or 'Pirfenidone' in the 'Find a medicine' search box and click on 'EdM' next to any of the Pirfenidone products). Alternatively, if you would like hard copies of this risk minimisation material or further information about this medicine, please contact please contact medinfo@accord-healthcare.com or by telephone +44(0)1271385257.

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