SANDOZ

SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN 'Pirfenidone'

Before initiating pirfenidone and in addition to reading the Summary of Product Characteristics (SmPC), please check each of the following:

Indications for use:
☐ The patient is an adult with a diagnosis of mild to moderate idiopathic pulmonary fibrosis
☐ The therapy will be commenced 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
☐ The patient has been advised to take Pirfenidone with food and to avoid grapefruit and grapefruit juice while they are being treated with Pirfenidone
Drug-induced Liver Injury:
Prior to initiation of treatment:
☐ The patient does not have severe hepatic impairment or end stage liver disease. Pirfenidone 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
☐ I am aware that elevations of serum transaminases can occur during treatment with pirfenidone
☐ 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 (after first six months) during treatment
☐ Patients who develop liver enzyme elevations will be closely monitored and the dose of pirfenidone 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 is known to be associated with photosensitivity reactions and that preventative 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 occur

Reporting of adverse events

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.

If you are aware of any suspected adverse reactions associated with the use of pirfenidone, including clinically significant photosensitivity reactions and skin rashes, drug-induced liver injury, clinically significant abnormal liver function tests and any other clinically significant adverse drug reactions (ADRs), please report such information to the MHRA via:

- the Yellow Card website https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ .

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to Sandoz via adverse.event.uk@sandoz.com

or

online through the pharmacovigilance intake (PVI) tool at https://pvi1j.solutions.iqvia.com.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, batch number and product brand name.

Further information

Please refer to Pirfenidone SPC for full prescribing information which can be found on the Electronic Medicine Compendium website www.medicines.org.uk/emc/

This educational material is provided by Sandoz Ltd and is mandatory as a condition of the marketing authorisation in order to further minimise important selected risks.

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