LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Pirfenidone Newbury (pirfenidone)

# SE/H/2230/01-02/DC

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# Summary Public Assessment Report

Pirfenidone Newbury
pirfenidone

Film-coated tablet, 267 mg, 801 mg

This is a summary of the public assessment report (PAR) for Pirfenidone Newbury. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Pirfenidone Newbury and what is it used for?**

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Esbriet.

The product is used in the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) in adults.

**How does Pirfenidone Newbury work?**

Pirfenidone Newbury contains the active substance pirfenidone and it is used for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) in adults.

IPF is a condition in which the tissues in the lungs become swollen and scarred over time, and as a result makes it difficult to breathe deeply. This makes it hard for the lungs to work properly. Pirfenidone Newbury helps to reduce scarring and swelling in the lungs, and helps breathe better.

**How is Pirfenidone Newbury used?**

The pharmaceutical form is film-coated tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

**What benefits of Pirfenidone Newbury have been shown in studies?**

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Esbriet. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects from Pirfenidone Newbury?**

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

**Why is Pirfenidone Newbury approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Esbriet, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Pirfenidone Newbury?"

**What measures are being taken to ensure the safe and effective use of Pirfenidone Newbury?**

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

<u>Additional risk minimisation measures (including educational material)</u>
The educational material should contain the following key elements:

The MAH must ensure that at launch all physicians who are expected to prescribe Pirfenidone Newbury are provided with a physician information pack containing the following:

- Product information (SPC)
- Physician information (safety checklists)
- Patient information (PIL)

The safety checklist about Pirfenidone Newbury should contain the following key elements related to liver function, drug-induced liver injury and photosensitivity:

*Liver function, drug-induced liver injury*

- Pirfenidone Newbury is contraindicated in patients with severe hepatic impairment or end stage liver disease.
- Elevations of serum transaminases can occur during treatment with Pirfenidone Newbury
- There is a need to monitor liver function tests prior to initiation of treatment with Pirfenidone Newbury and at regular intervals thereafter.
- Close monitoring is required of any patients who develop liver enzyme elevation with appropriate dose adjustment or discontinuation.
- Prompt clinical evaluation and liver function tests for patients who develop signs or symptoms of liver injury.

*Photosensitivity*

- Patients should be informed that Pirfenidone Newbury 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

The physician information should encourage the prescribers to report serious adverse reactions and clinically significant ADRs of special interest including:

- Photosensitivity reactions and skin rashes
- Abnormal liver function tests
- Drug-induced liver injury
- Any other clinically significant ADRs based on the judgment of the prescriber

**Other information about Pirfenidone Newbury**

The full PAR for Pirfenidone Newbury can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Pirfenidone Newbury , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-09.