LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pirfenidon Cipla
(pirfenidone)

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pirfenidone

Film-coated tablet, 267 mg, 801 mg

This is a summary of the public assessment report (PAR) for Pirfenidon Cipla. 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 Pirfenidon Cipla 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 contains the active substance pirfenidone and it is used for the treatment of Idiopathic Pulmonary Fibrosis (IPF) in adults.

How does Pirfenidon Cipla work?

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

How is Pirfenidon Cipla used?

The pharmaceutical form is film-coated tablet 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 Pirfenidon Cipla 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 Pirfenidon Cipla?

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

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Pirfenidon Cipla 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 Pirfenidon Cipla?”.

What measures are being taken to ensure the safe and effective use of Pirfenidon Cipla?

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.

The MAH must ensure that at launch all physicians who are expected to prescribe the product are provided with additional risk minimisation measures in the form of a physician information pack containing the product information (SPC), physician information (safety checklists) and patient information (PIL). The safety checklist should contain specific key elements related to liver function, drug-induced liver injury and photosensitivity.

Other information about Pirfenidon Cipla

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

This summary was last updated in 2024-01.