Pulmosis™

Pirfenidone

2038

Presentation
Pulmosis™ 267 capsule: Each capsule contains Pirfenidone BP 267 mg.
Pulmosis™ 267 tablet: Each tablet contains Pirfenidone BP 267 mg.
Pulmosis™ 534 tablet: Each tablet contains Pirfenidone BP 534 mg.
Pulmosis™ 801 tablet: Each tablet contains Pirfenidone BP 801 mg.

Description
Pirfenidone is an anti-fibrotic drug for the treatment of idiopathic pulmonary fibrosis (IPF). It is assumed that it works by reducing lung fibrosis through down regulation of the production of growth factors and procollagens.

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

2038

Indications
Pirfenidone is indicated for the treatment of idiopathic pulmonary fibrosis.

Dosage & Administration
- Recommended dosage: The recommended daily maintenance dosage of pirfenidone is 801 mg three times daily taken with food. Doses should be taken at the same time each day.
- Upon initiation of treatment, full dose should be titrated over a 14-day period as follows:

Treatment days	Dosage
Days 1 through 7	267 mg three times a day with meals
Days 8 through 14	534 mg three times a day with meals
Days 15 onward	801 mg three times a day with meals

Dosages above 2403 mg/day are not recommended for any patient.

Patients who miss 14 or more days of pirfenidone should be re-initiate treatment by undergoing the initial 2 week titration regimen up to full maintenance dosage. For the treatment interruption of less than 14 days, the dosage prior to the interruption can be resumed.

Use in pregnancy and lactation
Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. It is not known whether it is excreted in human milk.

Use in specific population
No dosage adjustment is required for geriatric patient. Pirfenidone should be used with caution in patients with mild to moderate hepatic and renal impairment. There is no relevent use of Pirfenidone in the paediatric population for the indication of IPF.

Side effects
The most common adverse reactions are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastro-esophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia etc.

Drug interaction
The concomitant administration of Fluvoxamine, Ciprofloxacine or other strong and moderate CYP1A2 inhibitors with Pirfenidone are not recommended because they significantly increase exposoure to pirfenidone.

Precautions
- Elevated liver enzymes: ALT, AST, and bilirubin elevations have occurred with Pirfenidone. Monitor ALT, AST and bilirubin before and during treatment. Temporary dosage reductions or discontinuations may be required.
- Photosensitivity and rash: Photosensitivity and rash have been noted with Pirfenidone. Avoid exposure to sunlight and sunlamps. Wear sunscreen and protective clothing daily. Temporary dosage reductions or discontinuations may be required.
- Gastrointestinal disorder: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease and abdominal pain are more frequently reported by patients in the treatment with Pirfenidone.

Contraindications
- History of angioedema with Pirfenidone
- Concomitant use of Fluvoxamine
- Severe hepatic impairment or end stage liver disease
- Severe renal impairment (CrCl <30 ml/min) or end stage renal disease requiring dialysis

Storage
Do not store above 30^0 C. Keep away from light and out of the reach of children.

Commercial pack
Pulmosis™ 267 capsule: Each box contains 3 blister strips of 10 capsules.
Pulmosis™ 267 tablet: Each box contains 3 blister strips of 10 tablets.
Pulmosis™ 534 tablet: Each box contains 2 blister strips of 10 tablets.
Pulmosis™ 801 tablet: Each box contains 1 blister strip of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
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PMC V.N.01