Pulmova

Pirfenidone BP

COMPOSITION

Pulmova 267 Tablet: Each film coated tablet contains Pirfenidone BP 267 mg.
Pulmova 801 Tablet: Each film coated tablet contains Pirfenidone BP 801 mg.

PHARMACOLOGY

The mechanism of action of Pirfenidone has not been fully established. However,existing data suggest that Pirfenidone exerts both antifibrotic and anti-inflammatory properties in a variety of in vitro systems and animal models of pulmonary fibrosis.
Pirfenidone attenuates fibroblast proliferation, production of fibrosis-associated proteins and cytokines and the increased biosynthesis and accumulation of extracellular matrix in response to cytokine growth factors such as transforming growth factor-beta (TGF-β) and platelet-derived growth factor (PDGF).

INDICATIONS

It is indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

DOSAGE AND ADMINISTRATION

Upon initiating treatment, the dose should be titrated to the recommended daily dose of 2403 mg/day with food over a 14-day period as follows:

Days 1 to 7: 267 mg three times daily (801 mg/day).
Days 8 to 14: 534 mg three times daily (1602 mg/day).
Day 15 onward: 801 mg three times daily (2403 mg/day).

Doses above 2403 mg/day are not recommended for any patient.
Patients who miss 14 consecutive days or more of it should re-initiate therapy by undergoing the initial 2 week titration regimen up to the recommended daily dose.
For treatment interruption of less than 14 consecutive days, the dose can be resumed at the previous recommended daily dose without titration.

CONTRAINDICATIONS

It is contraindicated in following states:
- Hypersensitivity to the Pirfenidone or to any of its excipients of it.
- History of angioedema with Pirfenidone.
- Concomitant use of Fluvoxamine.
- Severe hepatic impairment or end-stage liver disease.
- Severe renal impairment.

WARNING & PRECAUTION

Hepatic function: Liver function tests (ALT, AST and bilirubin) should be performed prior to the initiation of treatment with it and subsequently at monthly intervals for the first 6 months and then every 3 months thereafter.

Drug-induced liver injury: Liver function tests should be performed in patients who report symptoms like liver injury including fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice.

Hepatic impairment: It should be used with caution in patients with pre-existing mild to moderate hepatic impairment.

Photosensitivity reaction and rash: Exposure to direct sunlight should be avoided or minimized during treatment with Pirfenidone. Patients should be instructed to use a sunblock daily to wear clothing that protects against sun exposure and to avoid other medicinal products known to cause photosensitivity.

Severe skin reactions: If the patient has developed Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) with the use of it, treatment with Pirfenidone must not be restarted and should be permanently discontinued.

Angioedema/Anaphylaxis: Patients who develop signs or symptoms of angioedema or severe allergic reactions following the administration of it should immediately discontinue treatment.

Dizziness: Dizziness has been reported in patients taking Pirfenidone. Therefore, patients should know how they react to this medicinal product before they engage in activities requiring mental alertness or coordination. If dizziness does not improve or if it worsens in severity, dose adjustment or even discontinuation of Pirfenidone may be warranted.

Fatigue: Fatigue has been reported in patients taking Pirfenidone.

Weight loss: Weight loss has been reported in patients treated with Pirfenidone. Physicians should monitor the patient's weight and when appropriate encourage increased caloric intake if weight loss is considered to be of clinical significance.

Hyponatraemia: Hyponatraemia has been reported. Regular monitoring of the relevant laboratory parameters is recommended, especially in the presence of evocative signs and symptoms such as nausea, headache or dizziness.

SIDE EFFECTS

The most frequently reported side effects are nausea, rash, diarrhoea, fatigue, dyspepsia, decreased appetite, headache and photosensitivity reactions.

USE IN PREGNANCY & LACTATION

During pregnancy: There are no data on the use of Pirfenidone in pregnant women. As a precautionary measure, it is preferable to avoid the use of Pirfenidone during pregnancy.
Lactation: It is unknown whether Pirfenidone or its metabolites are excreted in human milk. A decision must be made whether to discontinue breastfeeding or to discontinue it, taking into account the benefit of breastfeeding for the child and the benefit of the therapy for the mother.

USE IN CHILDREN & ADOLESCENTS

There is no relevant use of it.

DRUG INTERACTIONS

Fluvoxamine and inhibitors of CYP1A2: Fluvoxamine should be discontinued prior to the initiation of Pirfenidone and avoided during its therapy due to the reduced clearance of Pirfenidone. Other therapies that are inhibitors of both CYP1A2 and one or more other CYP isoenzymes involved in the metabolism of Pirfenidone (e.g., CYP2C9, 2C19, and 2D6) should be avoided during Pirfenidone treatment.
Cigarette smoking and inducers of CYP1A2: Patients should be encouraged to discontinue the use of strong inducers of CYP1A2 and to stop smoking before and during treatment with Pirfenidone.

OVERDOSAGE

In the event of a suspected overdose, supportive medical care should be provided including monitoring of vital signs and close observation of the clinical status of the patient.

STORAGE

Store below 30°C temperature in a cool & dry place. Keep out of the reach of children.

HOW SUPPLIED

Pulmova 267 Tablet: Each box contains 20 tablets in Alu-PVDC blister pack.
Pulmova 801 Tablet: Each box contains 10 tablets in Alu-PVDC blister pack.

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Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.

NIPRO JMI Pharma