

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Pirfenidone Sandoz® 267 mg
Film-coated tablets

Active ingredient:
Each film-coated tablet contains:
pirfenidone 267 mg

For inactive ingredients and allergens in the medicine: see section 2 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Pirfenidone Sandoz is used for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) in adults.

Therapeutic group: Pirfenidone Sandoz is an immunosuppressant.

Idiopathic pulmonary fibrosis is a condition in which the lung tissue becomes swollen and scarred over time and as a result, it is difficult to breathe deeply. This makes it hard for the lungs to function properly. **Pirfenidone Sandoz** helps to reduce scarring in the lungs, and helps you breathe better.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are allergic (sensitive) to the active ingredient pirfenidone, or to any of the other ingredients in the medicine (see section 6 'Further Information')
- you have previously experienced angioedema with pirfenidone, including symptoms such as swelling of the face, lips and/or tongue which may be associated with breathing difficulties or wheezing
- you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder)
- you have a severe or end-stage liver disease
- you have a severe or end-stage kidney disease requiring dialysis

If any of the aforementioned conditions apply to you, do not use **Pirfenidone Sandoz**. If you are unsure, consult the attending doctor or pharmacist.

Special warnings regarding use of the medicine:

- Consult the doctor before taking **Pirfenidone Sandoz**.
- You may become more sensitive to sunlight (photosensitivity reaction) when taking **Pirfenidone Sandoz**. Avoid exposure to the sun (including sunlamps) while taking **Pirfenidone Sandoz**. Use a sunscreen daily and cover your arms, legs and head to reduce exposure to sunlight (see section 4 'Side Effects').
- Inform your doctor if you suffer from kidney problems.
- Inform your doctor if you suffer from mild to moderate liver problems.
- **Pirfenidone Sandoz** may cause dizziness and tiredness. Exercise caution when performing activities for which you have to be alert and functioning.
- **Pirfenidone Sandoz** can cause weight loss. Your doctor will monitor your weight while you are taking the medicine.
- Stevens-Johnson syndrome and toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with **Pirfenidone Sandoz** treatment. Stop using **Pirfenidone Sandoz** and seek medical attention immediately if you notice any of the symptoms related to the serious skin reactions described in section 4.

Smoking

You should stop smoking before and during the treatment with **Pirfenidone Sandoz**. Smoking cigarettes may reduce the effect of the medicine.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18.

Tests and follow-up

Pirfenidone Sandoz may cause severe liver problems and some cases have been fatal. You will need to undergo a blood test before you start taking the medicine, once a month for the first six months of treatment and once every three months thereafter while taking this medicine, in order to check that your liver is functioning properly. It is important that you undergo these routine blood tests for as long as you are taking **Pirfenidone Sandoz**.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor or pharmacist if you are taking the following medicines, since they may alter the effect of **Pirfenidone Sandoz**:

- Medicines that may increase the side effects of **Pirfenidone Sandoz**:
 - enoxacin (a certain type of antibiotic)
 - ciprofloxacin (a certain type of antibiotic)
 - amiodarone (used to treat certain types of heart disease)
 - propafenone (used to treat certain types of heart disease)
 - fluvoxamine (used to treat depression and obsessive compulsive disorder)
- Medicines that may reduce the medicine effectiveness:
 - omeprazole (for the treatment of conditions such as indigestion and gastroesophageal reflux)
 - rifampicin (a certain type of antibiotic)
- Do not take other medicines such as tetracycline antibiotics (e.g., doxycycline), which may make you more sensitive to sunlight.

Using the medicine and food

Swallow the tablets whole with water, during or after a meal, to reduce side effects such as nausea and dizziness (see section 4 'Side Effects').

Do not drink grapefruit juice during treatment with **Pirfenidone Sandoz**. Grapefruit juice may prevent **Pirfenidone Sandoz** from working properly.

Pregnancy and breastfeeding

As a precautionary measure, it is preferable to avoid using **Pirfenidone Sandoz** if you are pregnant, planning a pregnancy or think you may be pregnant, since the risks to the fetus are unknown. If you are breastfeeding, or plan to breastfeed, inform the doctor or pharmacist before taking **Pirfenidone Sandoz**. It is not known whether the medicine passes into breast milk. In case you decide to breastfeed, the doctor will discuss with you the risks and benefits of taking the medicine while breastfeeding.

Driving and using machinery

Do not drive or operate machinery if you feel dizzy or tired after taking **Pirfenidone Sandoz**.

Important information about some of this medicine's ingredients This medicine contains less than 1 mmol (23 mg) sodium per tablet, therefore it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions. You should check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

A specialist physician experienced in the diagnosis and treatment of idiopathic pulmonary fibrosis will decide on the commencement of treatment with **Pirfenidone Sandoz** preparation and will monitor the treatment.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
The medicine will usually be given to you in increasing dosages as follows:

- for the first 7 days of treatment: take a dose of 267 mg, 3 times a day with a meal (a total of 801 mg/day)
- from day 8 to day 14: take a dose of 534 mg (two **Pirfenidone Sandoz** 267 mg units), 3 times a day with a meal (a total of 1602 mg/day)
- from day 15 onwards (maintenance dosage): take 801 mg 3 times a day with a meal (a total of 2403 mg/day)

The usual daily maintenance dosage of **Pirfenidone Sandoz** is 801 mg (one **Pirfenidone Sandoz** 801 mg tablet), 3 times a day with a meal, a total of 2403 mg/day.

Swallow the tablets whole with water, during or after a meal, to reduce the risk of side effects such as nausea and dizziness. Contact your doctor if symptoms continue.

Do not exceed the recommended dose.

Dosage reduction due to side effects:

The doctor may reduce the dosage if you suffer from side effects such as abdominal problems, skin reactions to sunlight or sunlamps, or significant changes in liver enzymes.

If you accidentally took a higher dosage

If you have accidentally taken a higher dosage or if a child has accidentally swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take the medicine at the required time, take it as soon as you remember, but separate each dose by at least 3 hours.

Do not take a double dose to compensate for the forgotten one. Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

In certain situations, the doctor will advise you to stop taking **Pirfenidone Sandoz**.

If for any reason you have to stop taking **Pirfenidone Sandoz** for more than 14 consecutive days, the doctor will restart treatment with **Pirfenidone Sandoz** 267 mg preparation and will instruct you to first take 1 unit 3 times a day, and will then gradually increase the dosage to 801 mg, 3 times a day.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Pirfenidone Sandoz** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop taking Pirfenidone Sandoz and seek medical attention immediately if you notice any of the following signs or symptoms:

- swelling of the face, lips and/or tongue, itching, urticaria, breathing difficulties or wheezing, or fainting sensation, which are signs of angioedema, a severe allergic reaction or anaphylaxis.
- yellowing of the eyes or skin, dark urine, which may also be accompanied by itching of the skin, pain in the upper right side of the abdomen, loss of appetite, bleeding or bruising more easily than in the past, or feeling tired. These may be signs of impaired liver function and can indicate liver injury, which is an uncommon side effect of **Pirfenidone Sandoz**.
- reddish non-elevated, or circular patches on the trunk, often with central blisters, skin peeling, ulcers in mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome or toxic epidermal necrolysis].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Additional side effects

Inform the doctor if you experience any side effect.

Very common side effects (may affect more than 1 in 10 patients):

- infections of the throat or the airways going into the lungs and/or sinusitis
- nausea
- stomach problems such as acid reflux, vomiting, and feeling constipated
- diarrhea
- indigestion or abdominal pain
- weight loss
- decreased appetite
- difficulty sleeping
- tiredness
- dizziness
- headache
- shortness of breath
- cough
- aching joints

Common side effects (may affect up to 1 in 10 patients):

- bladder infections
- feeling sleepy
- changes in sense of taste
- hot flushes
- stomach problems, such as feeling bloated, abdominal pain and discomfort, heartburn, and flatulence
- blood tests that may show increased levels of liver enzymes
- skin reactions after going out in the sun or using sunlamps
- skin problems, such as itching, skin redness, red skin, dry skin and skin rash
- muscle pain
- feeling weak or lack of energy
- chest pain
- sunburns

Uncommon side effects (may affect up to 1 in 100 patients):

- low blood sodium level which may cause headache, dizziness, confusion, weakness, muscle cramps or nausea and vomiting
- blood tests which may show a decrease in white blood cells

If a side effect occurs, if any side effect worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Do not dispose of medicines into the wastewater or into a household waste bin. Ask the pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Storage conditions:

Store below 25°C.

Shelf life after first opening the bottle packaging:

Pirfenidone Sandoz 267 mg – 3 months

Pirfenidone Sandoz 801 mg – 2 months

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Tablet composition:

pregelatinised starch, croscarmellose sodium (E468), hydroxypropyl cellulose (E463), magnesium stearate (E572), silicon dioxide (E551).

Tablet coating:

267 mg:

Opadry yellow (85F220100): polyvinyl alcohol – part. hydrolyzed (E1203), titanium dioxide (E171), macrogol 3350, talc (E553B) and iron oxide yellow (E172).

801 mg:

Opadry pink (85F240048): polyvinyl alcohol – part. hydrolyzed (E1203), titanium dioxide (E171), macrogol 3350, talc (E553B), iron oxide yellow (E172), iron oxide red NF(E172) and iron oxide black NF(E172).

What the medicine looks like and the contents of the package:

Pirfenidone Sandoz 267 mg film-coated tablets: a yellow, oval, biconvex tablet, debossed with 'SD267' on one side.

Pirfenidone Sandoz 801 mg film-coated tablets: a dark pink, oval, biconvex tablet, debossed with 'SD801' on one side.

Pirfenidone Sandoz 267 mg is available in blister packaging containing 21, 42 or 63 film-coated tablets.

Pirfenidone Sandoz 801 mg is available in blister packaging containing 21, 63 or 84 film-coated tablets or in bottle packaging containing 90 film-coated tablets.

Not all package types and package sizes may be marketed.

License Holder and Importer's name and address: Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel.

Revised in April 2024.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Pirfenidone Sandoz 267 mg film-coated tablets: 175-20-37557-99

Pirfenidone Sandoz 801 mg film-coated tablets: 175-21-37558-99