

Pirfenidone Tablets, 267 mg and 801 mg

S. No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Pirfenidone tablets are indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
2	Dosage	What is the recommended dosage?	<p>Conduct liver function tests prior to initiating treatment with pirfenidone tablets.</p> <p><u>DOSAGE AND ADMINISTRATION</u> Recommended Dosage: The recommended daily maintenance dosage of pirfenidone tablet is 801mg three times daily for a total of 2403 mg/day.</p> <p>Doses should be taken with food at the same time each day.</p> <p>Upon initiation of treatment, titrate to the full dosage of 2403 mg/day over a 14-day period as follows: Dosage Titration for Pirfenidone tablets in Patients: Day 1-7: 267 mg three times daily (801 mg/day). Day 8-14: 534 mg three times daily (1602 mg/day). Day 15 onwards: 801 mg three times daily (2403 mg/day)</p> <p>Dosages above 2403 mg/day are not recommended for any patient. Patients should not take 2 doses at the same time to make up for a missed dose. Patients should not take more than 3 doses per day.</p> <p>Dosage Modifications are required upon experiencing Adverse Reactions. For complete details, please refer to Prescribing Information.</p>
3	Administration	Use in Pediatric Population	Safety and effectiveness of pirfenidone in pediatric patients have not been established.
4	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between older and younger patients. No dosage adjustment is required based upon age.
5	Mechanism	Mechanism of Action	The mechanism of action of pirfenidone in the treatment of IPF has not been established.

6	Warning	Warnings and Precautions	<ul style="list-style-type: none"> • Patients should let their doctor know if they have symptoms such as yellowing of skin or eyes, dark or brown urine, pain on the upper right side of stomach area, bleeding or bruising more easily than normal, or increased fatigue. Regular blood tests are required to check liver. • Photosensitivity and rash: Avoid exposure to sunlight and sunlamps. Wear sunscreen and protective clothing daily. • Gastrointestinal disorders: pirfenidone may cause Nausea, vomiting, diarrhea, dyspepsia, gastroesophageal reflux disease, and abdominal pain have occurred with pirfenidone.
7	Lactation	Use in Lactation	<p>Risk Summary Patients should let their doctor know if breastfeeding or plan to breastfeed. Patient and their doctor should decide if patient will take pirfenidone tablets.</p>
8	Pregnancy	Use in Pregnancy	Patients should let their doctor know if pregnant or plan to become pregnant. It is not known if pirfenidone tablets will harm patient's unborn baby.
9	Storage	Storage and Handling?	<p>It is recommended to Store the tablets at 25°C (77°F). Temperature excursions permitted to 15-30°C (59-86°F).</p> <p>Keep the bottle tightly closed. Do not use if the seal over the bottle opening is broken or missing. Safely throw away any pirfenidone that is out of date or no longer needed.</p>
10	Contraindication	What are the contraindications of (medication)?	None
Pharmaceutical Particulars			
11	Pharmaceutical Form	How Supplied	<p>267 mg Pirfenidone tablets are white colored, oval shaped, film coated tablets debossed with "M" on one side and "PF1" on other side.</p> <p>801 mg Pirfenidone tablets are white colored, oval shaped, film coated tablets debossed with "M" on one side and "PF3" on other side. The film-coated tablets are supplied in bottles.</p> <ul style="list-style-type: none"> • NDC 72205-181-36, carton containing 3 bottles, each containing thirty 267 mg tablets (90 tablets total) with a child-resistant closure • NDC 72205-181-38, carton containing 9 bottles, each containing thirty 267 mg tablets (270 tablets total) with a child-resistant closure • NDC 72205-181-90, carton containing 1 bottle, each containing ninety 267 mg tablets with a child-resistant closure • NDC 72205-181-26, carton containing 3 bottles, each containing ninety 267 mg tablets (270 tablets total) with a child-resistant closure • NDC 72205-182-36, carton containing 3 bottles, each containing thirty 801 mg tablets (90 tablets total) with a child-resistant closure • NDC 72205-182-90, carton containing 1 bottle, each containing ninety 801 mg tablets with a child-resistant closure

12	Ingredients	Active and Inactive	Active ingredient: pirfenidone Inactive ingredients: croscarmellose sodium, colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, titanium dioxide, macrogol (polyethylene glycol) and talc.
Allergens			
13	Ingredients	Does it contain Gluten?	No
14	Ingredients	Does it contain alcohol?	API contains solvents within the limits as per ICH
15	Ingredients	Does it contain dyes?	Yes, it contains titanium dioxide.
16	Ingredients	Does it contain Lactose?	No
17	Ingredients	Does it contain Nuts?	No
18	Ingredients	Does it contain Preservatives?	No
19	Ingredients	Does it contain Soy products?	No
20	Ingredients	Does it contain peanut?	No
21	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
22	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
23	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
24	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
25	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products
26	Miscellaneous	May I know where is this product manufactured?	Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA

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