Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
YOU ARE DETERMINED
That’s why you’re taking action

Being diagnosed with idiopathic pulmonary fibrosis (IPF) can be overwhelming. But learning about your condition and taking action with Esbriet® (pirfenidone) may help you feel more in control.

The goal of this brochure is to help you understand IPF and what to expect with Esbriet so you can get the most from your treatment.

What is Esbriet?

Esbriet (pronounced es-BREE-et) is an FDA-approved prescription medicine for the treatment of IPF.

In clinical studies of people with IPF, Esbriet helped preserve lung function by slowing disease progression.

If you have not already, ask your doctor if Esbriet is right for you.

SELECT IMPORTANT SAFETY INFORMATION

Before you take Esbriet, tell your doctor about all of your medical conditions, including if you:

- have liver problems;
- have kidney problems;
- are a smoker;
- are pregnant or plan to become pregnant (it is not known if Esbriet will harm your unborn baby);
- are breastfeeding or plan to breastfeed (it is not known if Esbriet passes into your breast milk). You and your doctor should decide if you will take Esbriet or breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.
INFORMATION ABOUT ESBRIET® (PIRFENIDONE)

Why you should take action today
IPF is not only rare, it is also a progressive disease. This means it worsens over time. IPF is a disease that scars your lungs. This scarring cannot be undone. It is irreversible. IPF is also unpredictable. It is hard to know how quickly IPF will progress. It differs from person to person.

The I in IPF stands for “idiopathic,” which means its cause is unknown.

“Pulmonary” is another word for lung.

“Fibrosis” refers to scarring.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
What happens in IPF?

IPF is scarring of tissue in your lungs.

- This scarring, or fibrosis, may be the result of tiny injuries deep in your lungs that do not heal properly.

- These injuries lead to progressive scarring of tissue in the small air sacs in your lungs (called alveoli). This scarring, or fibrosis, causes the lungs to stiffen.

- Fibrosis may damage the lungs’ ability to exchange gases such as oxygen with the blood.

- IPF is progressive, which means that over time the scarring becomes more widespread and lung function declines. Doctors can’t predict how quickly this will happen. IPF progresses rapidly for some people and slowly for others.

What can I do?

You have an important part to play in taking a stand against IPF. Take an active role—stay informed and ask questions.

- Talk with your doctor about ways to support a healthy lifestyle and help manage your IPF symptoms:
  - Pulmonary rehabilitation, a combination of monitored exercise, nutrition and education, can be helpful for people with chronic lung diseases such as IPF.
  - Supplemental oxygen therapy may become an important part of managing your IPF.

- Help your family and close friends learn more about your condition.

- If you haven’t already, talk with your doctor about treatment for IPF.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
PRESERVING YOUR LUNG FUNCTION IS ESSENTIAL AND ESBRIET® (PIRFENIDONE) MAY HELP

Knowing what to expect is an important part of your treatment. In this section, you’ll learn more about the benefits and risks of Esbriet.
ESBRIET® (PIRFENIDONE) MAY HELP PRESERVE MORE OF YOUR LUNG FUNCTION

Although lung function that is lost cannot be restored, treatment may help maintain more of your lung function by slowing the progression of the disease.

- At the end of a 1-year clinical study of people with IPF, more than twice as many people who took Esbriet preserved baseline lung function, compared to those who did not take Esbriet.

How lung function was measured
In the clinical studies, the effect of Esbriet on lung function (how well the lungs work) was measured by forced vital capacity (FVC). FVC measures the amount of air you can exhale with force after you inhale as deeply as possible.

SELECT IMPORTANT SAFETY INFORMATION

What should I avoid while taking Esbriet?

- **Sunlight** Esbriet can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You could get a severe sunburn. Use sunscreen (SPF 50) and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn or a rash.

- **Smoking** Smoking may affect how well Esbriet works.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Esbriet® (pirfenidone) may help preserve more of your breathing capacity

- In a 1-year clinical study, people who took Esbriet had better breathing capacity, compared with those who did not take Esbriet (193 mL difference in FVC)

**Less Decline in FVC Volume for People Taking Esbriet**

- One 72-week study showed similar results
- Another 72-week study did not show a significant difference between people who took Esbriet and those who did not

**SELECT IMPORTANT SAFETY INFORMATION**

**What are the possible side effects of Esbriet?**

Esbriet may cause serious side effects, including:

- **Liver problems** Call your doctor right away if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea-colored) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal or feeling tired

Your doctor will do blood tests to check how your liver is working during your treatment with Esbriet.
Important things to keep in mind with IPF treatment

- IPF is progressive, so **slowing its decline** can be an important goal of treatment

- Starting and staying on Esbriet® (pirfenidone) treatment as prescribed by your doctor can be an important way to **help preserve more of the lung function you have today**

- Once you begin taking Esbriet, **you may not “feel” different**, because Esbriet does not treat the symptoms of IPF and does not reverse the scarring in your lungs

- **IPF worsens at different rates in different people.** With or without Esbriet, lung function may continue to decline. Remember, the goal is to slow the decline. Your doctor will conduct lung function tests to measure how IPF is affecting your lungs over time

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**SELECT IMPORTANT SAFETY INFORMATION**

**What are the possible side effects of Esbriet?**

Esbriet may cause serious side effects, including:

- Sensitivity to sunlight (photosensitivity) and rash
  See "What should I avoid while taking Esbriet?"

---

Key facts about Esbriet

- Three clinical studies evaluating the safety and effectiveness of Esbriet were reviewed by the FDA
- Esbriet is proven to help preserve lung function for some people with IPF
- Esbriet may cause serious side effects
- Esbriet has been used in more than **31,000** patients worldwide
POSSIBLE SIDE EFFECTS OF ESBRIET® (PIRFENIDONE)

When starting a new medicine, it is important to know about possible side effects. Some people may experience side effects when taking Esbriet. Here are some of the serious side effects experienced by people in clinical studies of Esbriet. Be sure to discuss any side effects and how to help manage them with your doctor.

Potential serious side effects

Call your doctor immediately if you experience any of these serious side effects:

- **Liver problems**
  - your skin or the white part of your eyes turn yellow
  - you have dark or brown (tea-colored) urine
  - you feel pain in the upper right side of your stomach area
  - you bleed or bruise more easily than normal
  - you feel tired

Your doctor will do blood tests to check how your liver is working during your treatment with Esbriet.

- **Sensitivity to sunlight and skin rash**
  Esbriet can cause your skin to sunburn more easily.

- **Stomach problems**
  Esbriet may cause nausea, vomiting, diarrhea, indigestion, heartburn and stomach pain.
Common side effects
In clinical studies, side effects that occurred in 10% or more of people treated with Esbriet® (pirfenidone) included:

- nausea
- rash
- stomach pain
- upper respiratory tract infection
- diarrhea
- fatigue
- headache
- indigestion
- dizziness
- vomiting
- decreased or loss of appetite
- gastroesophageal reflux disease (GERD)
- sinusitis
- sleeplessness
- weight loss
- joint pain

Tell your doctor immediately if you have any side effects while you are taking Esbriet. He or she may need to reduce your dose of Esbriet or ask you to stop taking it for a short time to help manage side effects.

- If you stop taking Esbriet for 14 or more days to help manage side effects
  - you will need to restart treatment with a low dose
  - then slowly increase to the maximum dose
- Your doctor may also ask you to permanently stop taking Esbriet

Managing certain side effects

Preventing sun sensitivity
Always use a broad-spectrum (UVA/UVB) sunscreen with SPF 50 or higher when outside. Reapply often throughout the day.

Avoid taking other medicines that can make your skin sensitive to the sun, the light from sunlamps and tanning beds.

Wear a hat and clothing that protects your skin, including your face, arms and legs.

Managing nausea and dizziness
Always take Esbriet® (pirfenidone) with food, as doing so may reduce side effects such as nausea and dizziness.
SOME SIDE EFFECTS MAY DECREASE

In the clinical studies of Esbriet® (pirfenidone), some side effects occurred soon after starting treatment, and/or decreased over time.

- **Stomach problems:** These were most often experienced early in the course of treatment—mostly in the first 3 months—and decreased over time. 2.2% of patients had to stop taking Esbriet because of stomach problems (vs. 1% with those not taking Esbriet)

- **Sensitivity to sunlight:** The majority of these reactions happened in the first 6 months on treatment. 9% of patients treated with Esbriet experienced sun sensitivity (vs. 1% not taking Esbriet)

These are not the only side effects. Be sure to talk to your healthcare provider immediately if you experience any side effects.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
HOW TO TAKE ESBRIE® (PIRFENIDONE)

When starting a new medicine, it can take time for your body to adjust. Starting with a small dose and slowly working up to a full dose over time can help.

Starting Esbriet

- When you start Esbriet, your doctor will slowly increase the dose over 2 weeks. This continues until you reach the full daily dose. This will allow your body time to get used to the medicine. (Increasing or decreasing the dose is called titration)
- The recommended full daily dose of Esbriet is 3 yellow tablets (267 mg each) taken 3 times each day with food
- Doses should be taken at the same time each day with food: in the morning, afternoon and evening
- The recommended full dose is 9 yellow tablets (267 mg each) every day

Make Esbriet part of your daily routine—take it with breakfast, lunch and dinner

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<th>Week</th>
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<th>(dinner)</th>
<th>Total yellow tablets each day</th>
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<td>9</td>
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SELECT IMPORTANT SAFETY INFORMATION

What are the possible side effects of Esbriet?

Esbriet may cause serious side effects, including:

- **Stomach problems** Esbriet may cause stomach problems such as nausea, vomiting, diarrhea, indigestion, heartburn and stomach pain. Tell your doctor right away if your stomach problems get worse or do not go away. Your doctor may need to change your dose of Esbriet

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
LEARN ABOUT AN OPTION WITH FEWER PILLS PER DAY

After you are doing well on the 9 yellow tablets (267 mg each) of Esbriet® (pirfenidone) a day, you and your doctor may want to talk about moving to a 3 tablet per day option.

Your doctor may suggest moving to fewer pills per day

- After the full daily dose of 3 yellow tablets 3 times a day is well tolerated, your doctor may prescribe 1 brown tablet (801 mg), taken 3 times a day with food.
- Each brown tablet has the same amount of medicine as 3 yellow tablets.

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<th>Esbriet 801 mg dosing schedule</th>
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<tr>
<td>Once well tolerated</td>
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</table>

Once you are doing well on 9 yellow tablets a day, ask your doctor if transitioning to 3 brown tablets is an option for you.

SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of Esbriet include feeling tired, insomnia, upper respiratory tract infections, sinusitis, headache, dizziness, decreased weight and decreased or loss of appetite. These are not all the possible side effects of Esbriet.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.
**DOSING (CONTINUED)**

- Esbriet® (pirfenidone) should be taken with a meal at the same times each day
  - Taking Esbriet with or at the end of a meal may help reduce certain side effects
- Your doctor will titrate (slowly increase) the dose over 2 weeks until you reach the recommended full daily dose. This will allow your body time to get used to the medicine
- If you experience side effects, talk with your healthcare provider, who may need to reduce your dose or ask you to stop taking it for a short time to help reduce side effects

> **Sticking to your dosing schedule is important**

Your doctor prescribed Esbriet to help preserve your lung function by slowing the progression of IPF

- This is why it is important to start Esbriet and continue taking it as directed
- If you experience side effects while taking Esbriet, talk to your doctor about ways to help manage them. Your doctor may adjust your dose as needed

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**About Esbriet**

Esbriet is a prescription medicine used to treat people with a lung disease called idiopathic pulmonary fibrosis (IPF). It is not known if Esbriet is safe and effective in children.

**SELECT IMPORTANT SAFETY INFORMATION**

*Before you take Esbriet, tell your doctor about all of your medical conditions, including if you:*

- have liver problems
- have kidney problems
- are a smoker
- are pregnant or plan to become pregnant (it is not known if Esbriet will harm your unborn baby)
- are breastfeeding or plan to breastfeed (it is not known if Esbriet passes into your breast milk)

You and your doctor should decide if you will take Esbriet or breastfeed.

*Tell your doctor about all the medicines you take,* including prescription and over-the-counter medicines, vitamins and herbal supplements.
SELECT IMPORTANT SAFETY INFORMATION
What should I avoid while taking Esbriet?

- **Sunlight** Esbriet can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You could get a severe sunburn. Use sunscreen (SPF 50) and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn or a rash.

- **Taking Esbriet with other medicines** that can make your skin sensitive to the sun, the light from sunlamps and tanning beds.

- **Smoking** Smoking may affect how well Esbriet works.

Important points to remember

- Your doctor should do certain blood tests before you start taking Esbriet® (pirfenidone) and periodically during treatment, to check how your liver is working.
- Take Esbriet exactly as your doctor tells you to take it.
- Your doctor may change your dosage of Esbriet as needed.
- Always take Esbriet with food to help reduce certain side effects.
- If you miss a dose of Esbriet, take it with food as soon as you remember:
  - **Do not** take 2 doses at the same time to make up for a missed dose.
  - **Do not** take more than 3 doses in a day.
- If you take too much Esbriet, call your doctor or go to the nearest hospital emergency room right away.
SIGN UP FOR ONGOING SUPPORT

Because every IPF journey is different, the Esbriet® Inspiration Program™ delivers information and inspiration to you in 3 ways:

- Email
- Mailings sent home
- 24-Hour Nurse Support Line

It all comes to you over the course of several months, timed to where you are in your treatment. Here are some examples of what the program provides:

**Pillbox**

Gives you an easy way to remember to take Esbriet® (pirfenidone) when you start.

**Journal**

To help you schedule Esbriet with meals and write questions you may have for your doctor.

**Healthy recipes**

That highlight the importance of taking Esbriet with a meal.

**Inspiration**

From others just like you. Get encouragement and motivation from people taking Esbriet.
2 SIMPLEx WAYS TO SIGN UP

- Complete section 7 on your Patient Authorization and Notice of Release of Information (PAN) form

- Visit Esbriet.com/welcome

Remember: The information you receive as part of the Esbriet® Inspiration Program™ does not replace discussions with your doctor. Please contact your doctor with any questions about your condition and treatment options, including Esbriet® (pirfenidone), as well as any side effects you may experience while taking Esbriet.

Be sure to answer phone calls. These calls may be related to your treatment:

- Esbriet Access Solutions for financial support and services you need to get your medicine

- Your specialty pharmacy, a special type of pharmacy that ships your medicine directly to your home. You may receive calls to set up your deliveries

We are here when you need us. Nurses are available to help answer your questions about Esbriet 24 hours a day. Call 1-844-693-7274 and press 1 to speak with a nurse.

Schedule an in-person education session
To learn about your condition and Esbriet with a Clinical Coordinator, call the Esbriet Support team at 1-844-693-7274 and press 3.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
ESBRIET ACCESS SOLUTIONS IS HERE TO HELP YOU

Esbriet Access Solutions is a resource for people who are taking Esbriet® (pirfenidone). Esbriet Access Solutions can:

- **Check your coverage**
  Esbriet Access Solutions can find out:
  - If your healthcare plan covers Esbriet
  - How much your co-pay will be for Esbriet

- **Connect you to financial assistance options**
  If you are worried about paying for Esbriet, there might be options to help you. We can help you understand those options.

Esbriet is a specialty drug. **You cannot pick it up from your local drugstore.** It will be delivered to your home from a specialty pharmacy.

**Your specialty pharmacy will call you to schedule delivery of Esbriet.** Be sure to answer this call, since its phone number may show as “unknown,” “blocked,” or “restricted.” Schedule the shipment for a time when you will be home. The pharmacy cannot leave your prescription outside.

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**Genentech Access Solutions can refer you to one of the below:**

<table>
<thead>
<tr>
<th>FOR PEOPLE WITH:</th>
<th>WE OFFER:</th>
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<tbody>
<tr>
<td><strong>Commercial Insurance</strong></td>
<td>The Esbriet Co-pay Card Program*&lt;br&gt;Pay just $5 per monthly Esbriet prescription, if you qualify.†</td>
</tr>
<tr>
<td><strong>Public insurance or Commercial insurance</strong></td>
<td>Referrals to independent co-pay assistance foundations‡&lt;br&gt;Independent co-pay assistance foundations can provide a grant to help you pay for your medication</td>
</tr>
<tr>
<td><strong>No insurance or Public insurance or Commercial insurance</strong></td>
<td>The Genentech Access to Care Foundation (GATCF)§&lt;br&gt;GATCF can help you receive Esbriet free of charge, if you qualify</td>
</tr>
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</table>

*In order to be eligible for the Esbriet Co-pay Card Program, you must confirm that you meet the eligibility criteria and agree to the rules set forth in the terms and conditions for the program. Please visit EsbrietCopay.com for the full list of terms and conditions.

†The program covers the rest of your out-of-pocket costs for Esbriet, up to a $25,000 yearly limit.

‡Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. We do not endorse or show financial preference for any particular foundation. The foundations we refer you to are not the only ones that might be able to help you.

§If you have health insurance, you must have already tried other types of patient assistance to qualify for free medicine from GATCF. This includes Genentech co-pay cards and support from co-pay assistance foundations. You must also meet specific criteria.

**To learn more about Esbriet Access Solutions,** call 1-844-ESBRIET (844-372-7438) or visit Genentech-Access.com/Esbriet.
FREQUENTLY ASKED QUESTIONS ABOUT ESBRIET® (PIRFENIDONE)

What is Esbriet?
Esbriet is an FDA-approved prescription medicine for people with idiopathic pulmonary fibrosis (IPF).

What are the benefits of Esbriet that were shown in clinical studies?
In clinical studies, Esbriet helped preserve lung function by slowing disease progression. This is why it is important to continue taking Esbriet as directed by your doctor.

See pages 8–15 to learn more about the benefits of Esbriet.

What are the possible side effects of Esbriet?
Some people may have serious side effects when taking Esbriet, including liver problems, sensitivity to sunlight (including sunlamps) or stomach problems. Other reported side effects that occurred in 10% or more of people treated with Esbriet in clinical studies included feeling tired, headache, dizziness and a decreased or loss of appetite. In the clinical studies of Esbriet, some side effects occurred soon after starting treatment, but decreased over time.

These are not all of the side effects reported with Esbriet. See pages 16–20 to learn more about possible side effects of Esbriet.

SELECT IMPORTANT SAFETY INFORMATION
What are the possible side effects of Esbriet?
Esbriet may cause serious side effects, including:

- **Liver problems** Call your doctor right away if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea-colored) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal or feeling tired

Your doctor will do blood tests to check how your liver is working during your treatment with Esbriet.

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
How will I know Esbriet® (pirfenidone) is working?
You may not feel different after starting Esbriet because Esbriet does not treat the symptoms of IPF. Your doctor prescribed Esbriet to help preserve your lung function by slowing the progression of IPF. Your doctor will monitor your lung function over time.

Why is staying on Esbriet treatment important?
It is important to do everything you can to preserve lung function, but it is hard to predict how your IPF will progress.
Starting and staying on Esbriet treatment, as prescribed by your doctor, may be an important way to help slow IPF progression.

How do I know that Esbriet is right for me?
Only you and your doctor can decide if Esbriet is right for you. If you are an adult who has been diagnosed with IPF, talk to your doctor about starting Esbriet.

How do I take Esbriet?
When you start Esbriet, your doctor will slowly increase the dose over 2 weeks until you reach the recommended full daily dose. This will allow your body time to get used to the medicine.
See pages 22–29 to learn more about how to take Esbriet.

How long has Esbriet been available in the United States?
The FDA approved Esbriet for treating IPF in October 2014.

How can I learn more about Esbriet?
Visit the Esbriet.com website to learn more about Esbriet and register for updates and additional information.

SELECT IMPORTANT SAFETY INFORMATION
What are the possible side effects of Esbriet?
Esbriet may cause serious side effects, including:
- Sensitivity to sunlight (photosensitivity) and rash
See “What should I avoid while taking Esbriet?”
DOSE TRACKER

Keep track of your Esbriet® (pirfenidone) dosing

Now that you’ve been prescribed Esbriet, it is important that you take Esbriet as directed by your doctor. The tracker on the following pages will help you get started on Esbriet. It is designed for patients taking yellow tablets (267 mg each).

When starting a new medicine, it can take time for your body to adjust. Starting with a small dose and slowing working up to a full dose over time can help. Remember to take it with a meal.

This tracker gives you a simple way to note the number of Esbriet yellow tablets you should take each day.

- When you start Esbriet, your doctor will slowly increase the dose over 2 weeks. This continues until you reach the recommended maximum daily dose. This will allow your body time to get used to the medicine.

- The recommended daily dose of Esbriet yellow tablets (267 mg each) is 3 tablets 3 times a day taken at the same times each day with meals—at breakfast, lunch and dinner—for a total of 9 yellow tablets each day.
HOW TO USE THIS TRACKER

Check the box each time you take a yellow Esbriet® (pirfenidone) tablet (267 mg each).

Use the space to note anything you want to keep track of—times you ate, how you felt after taking Esbriet, questions for your doctor, etc.

Questions about dosing? Call 1-844-My-Esbriet (844-693-7274).

Follow the Esbriet dosing schedule your doctor prescribed for you. It could look a lot like this schedule:

<table>
<thead>
<tr>
<th>Week</th>
<th>(breakfast)</th>
<th>(lunch)</th>
<th>(dinner)</th>
<th>Total yellow tablets each day</th>
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<td>1</td>
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Sample: Week 1

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<tr>
<td>Medication (Breakfast)</td>
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Week 1: Your notes

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**WEEK 1:**
Take 1 yellow tablet (267 mg) 3 times a day with a meal

✔ Check the box each time you take a yellow Esbriet® (pirfenidone) tablet (267 mg each).

<table>
<thead>
<tr>
<th>DATE</th>
<th>Medication (Breakfast)</th>
<th>Medication (Lunch)</th>
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**Week 1: Your notes**

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WEEK 2:
Take 2 yellow tablets (267 mg each) 3 times a day with a meal.

Check the box each time you take a yellow Esbriet® (pirfenidone) tablet (267 mg each).

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<thead>
<tr>
<th>DATE</th>
<th>Medication (Breakfast)</th>
<th>Medication (Lunch)</th>
<th>Medication (Dinner)</th>
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Week 2: Your notes

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### WEEK 3:
Take 3 yellow tablets (267 mg each) 3 times a day with a meal

**Check the box** each time you take a yellow Esbriet® (pirfenidone) tablet (267 mg each).

#### TRACKER

**WEEK 3:**

<table>
<thead>
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<th>DATE</th>
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**Week 3: Your notes**

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**After you have been doing well on 3 yellow tablets (267 mg each) 3 times a day, you can talk to your doctor about whether moving to the 1 brown tablet (801 mg), 3 times a day is an option for you.**

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
MY HEALTHCARE TEAM

It’s important to stay on your treatment plan and monitor your condition. Work with your healthcare team to track your treatment and symptoms.

To better prepare for discussions with your doctor, write down notes and questions to ask ahead of time. Tell your doctor how you are feeling and what symptoms you may be experiencing.

Remember: The information in this booklet does not replace discussions with your doctor. Please contact your doctor with any questions about your condition and treatment options, including Esbriet, as well as any side effects you may experience while taking Esbriet.
List important contact information here to keep all your contacts in one place. **Also be sure to enter important numbers on the fridge magnet enclosed in this kit.**

**Doctor**
Name ____________________________
Phone ____________________________
Email ____________________________

**Nurse**
Name ____________________________
Phone ____________________________
Email ____________________________

**Local pharmacy**
Name ____________________________
Phone ____________________________

**Insurance information**
Plan name ____________________________
Plan number ____________________________
Phone ____________________________

**Other healthcare providers**
Name ____________________________
Service ____________________________
Phone ____________________________
Email ____________________________

**24-Hour Nurse Support Line**
Phone 1-844-My-Esbriet (844-693-7274)

**Esbriet Access Solutions**
Phone 1-844-ESBRIET (844-372-7438)

**Specialty pharmacy for delivery of Esbriet® (pirfenidone)**
Name ____________________________
Phone ____________________________

Please see select Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Supporting you every step of the way

- To learn more about how Esbriet® (pirfenidone) may help, visit www.Esbriet.com
- Be sure to sign up for the Esbriet® Inspiration Program™ to receive ongoing support
- To schedule an in-person education session, call the Esbriet Support team at 1-844-693-7274 and press 3

NOTES

It’s important to know what to expect with your Esbriet treatment. Here are some suggested topics you may want to discuss with your doctor if you are taking Esbriet or considering treatment.

- Is treatment with Esbriet right for me?
- What is the best way to take Esbriet to help manage side effects?
- What is a realistic goal for my Esbriet treatment?
TAKE ACTION TO MANAGE YOUR CONDITION

▸ Take Esbriet® (pirfenidone) as directed by your doctor

▸ Enroll in the Esbriet® Inspiration Program™

▸ Learn about your condition and partner with your healthcare team

This kit is here to show you how.

You can also reach out to our 24-Hours Nurse Support Line, 24 hours a day, 7 days a week, by calling 1-844-693-7274 and pressing 1 to speak with a nurse.
Patient Information
ESBRIET (pirfenidone) capsules and film-coated tablets

What is ESBRIET?
ESBRIET is a prescription medicine used to treat people with a lung disease called idiopathic pulmonary fibrosis (IPF).

It is not known if ESBRIET is safe and effective in children.

Before you take ESBRIET, tell your doctor about all of your medical conditions, including if you:
• have liver problems
• have kidney problems
• are a smoker
• are pregnant or plan to become pregnant. It is not known if ESBRIET will harm your unborn baby.
• are breastfeeding or plan to breastfeed. It is not known if ESBRIET passes into your breast milk. You and your doctor should decide if you will take ESBRIET.

How should I take ESBRIET?
• Take ESBRIET exactly as your doctor tells you to take it.
• Your doctor may change your dose of ESBRIET as needed.
• Take ESBRIET with food at the same time each day. This may help to decrease your nausea and diziness.

ESBRIET 267 mg is supplied as either a white to off-white film-coated tablet. If you have been prescribed ESBRIET 267 mg, take it as follows:
• Take 1 ESBRIET 267 mg capsule or tablet 3 times each day for days 1 through 7.
• Take 2 ESBRIET 267 mg capsule or tablet 3 times each day for days 8 through 14.
• Take 3 ESBRIET 267 mg capsule or tablet 3 times each day on day 15 and each day after.

If you have been prescribed the brown 801 mg ESBRIET film-coated tablets, take it as follows:
• Take 1 brown 801 mg ESBRIET tablet 3 times each day.

What should I avoid while taking ESBRIET?
• Avoid sunlamps, tanning booths, and direct sunlight. ESBRIET can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You could get a severe sunburn. Use sunscreen (SPF 30) and wear a hat and clothing that cover your skin if you will be in sunlight. Talk to your doctor if you get sunburn or a rash.

• Avoid taking ESBRIET, with other medicines that can make your skin sensitive to the sun, the light from sunlamps and tanning beds.
• Avoid smoking. Smoking may affect how well ESBRIET works.

What are the possible side effects of ESBRIET?
ESBRIET may cause serious side effects, including:
• liver problems. Call your doctor right away if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea colored) urine, pain on the upper right side of your stomach, nausea, vomiting, stomach pain, swelling, bleeding or bruising more easily than normal, feeling tired.
• Your doctor will do blood tests to check how your liver is working during your treatment with ESBRIET.
• sensitivity to sunlight (photosensitivity) and rash. See “What should I avoid while taking ESBRIET?”
• stomach problems. ESBRIET may cause stomach problems such as nausea, vomiting, diarrhea, indigestion, heartburn, and stomach pain. Tell your doctor right away if your stomach problems get worse or do not go away. Your doctor may need to change your dose of ESBRIET.

The most common side effects of ESBRIET include feeling tired, insomia, upper respiratory tract infections, rhinitis, sneezing, headache, diziness, decreased weight and decreased or loss of appetite. These are not all the possible side effects of ESBRIET. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ESBRIET?
• Store ESBRIET capsules and tablets at room temperature, 77°F (25°C).
• Keep in a tightly closed container.

Safety throw away any ESBRIET that is out of date or no longer needed. Keep ESBRIET and all medicines out of reach of children.

General information about the safe and effective use of ESBRIET
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ESBRIET for a condition for which it was not prescribed. Do not give ESBRIET to other people, even if they have the same symptoms that you have. It may harm them. Ask your pharmacist or doctor for information about ESBRIET that is written for health professionals.

What are the ingredients in ESBRIET capsules?
Active ingredient: pirfenidone
Inactive ingredients: iron oxide black, iron oxide red, iron oxide yellow, propylene glycol, ammnonium hydroxide

What are the ingredients in ESBRIET film-coated tablets?
Active ingredient: pirfenidone
Inactive ingredients: microcrystalline cellulose, colloidal anhydrous silica, povidone, croscarmellose sodium, magnesium steara, propylene alcohol, titanium dioxide, magnesium polyvinyl glycol, talc, and iron oxide.

For more information, go to www.esbriet.com or call 1-888-835-3305.
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This Patient Information has been approved by the U.S. Food and Drug Administration.
Revised: January 2017
Reduced from GD 6 to 18. In these studies, pirfenidone at doses up to 3 and 2 times, respectively, the maximum tolerated dose (MTD), caused no statistically significant increases or decreases in mean maternal body weight gain, relative or absolute maternal organ weights, or fetal body weights. However, there were decreases in the number of live fetuses and an increase in the number of resorptions. No fetus was observed with a major malformation. The no-observed-effect level (NOEL) was 200 mg/kg/day for rats and 50 mg/kg/day for rabbits.

In a 24-month carcinogenicity study in Fischer rats, pirfenidone caused statistically significant dose-related increases of testicular and epididymal atrophy at doses of 10 and 100 mg/kg/day. This effect was not observed in a 12-month carcinogenicity study in male Sprague-Dawley rats at doses of 100 and 300 mg/kg/day. No carcinogenic effect was observed in a 2-year bioassay in mice (B6C3F1 hybrids) at doses up to 200 mg/kg/day.

In a 2-year carcinogenicity study in Sprague-Dawley rats, pirfenidone caused dose-related increases of testicular atrophy and epididymal weight at all dose levels studied. Histopathological examination revealed dose-related decreases in testes and epididymal weights and increases in the number of atrophic tubules and spermatogenic cysts. There were statistically significant increases in the incidence of testicular atrophy at 10, 30, and 100 mg/kg/day, and in the incidence of epididymal weight loss at 30 and 100 mg/kg/day. There were also statistically significant increases in the incidence of spermatogenic cysts at 30 and 100 mg/kg/day. The NOEL for testicular atrophy was 10 mg/kg/day and the NOEL for epididymal weight loss was 30 mg/kg/day.

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