

Patient Guide to Photodynamic Therapy (PDT) With PHOTOFRIN®

PDT with
photofrin[®]
(porfimer sodium) for Injection

Please see Important Safety Information and
full US Prescribing Information enclosed.

About This Guide

Photodynamic therapy (PDT) is a treatment for certain kinds of cancer that combines a drug, called a photosensitizing agent (PHOTOFRIN® [porfimer sodium]), with a specific type of light to kill cancer cells.

PDT with PHOTOFRIN® is approved to treat non-small-cell lung cancer (a type of lung cancer) in patients for whom usual treatments are not appropriate and to relieve symptoms in patients in whom the cancer obstructs the airway, or in which the cancer cells slightly invade surrounding tissues. PHOTOFRIN® is also approved to relieve symptoms of esophageal (food pipe) cancer when the cancer blocks the esophagus or when the cancer cannot be treated with laser alone.¹

This guide has been designed to help you understand how PDT with PHOTOFRIN® works and what side effects may occur. It also explains what you need to do before and after treatment to prevent photosensitivity (an abnormally strong sunburn-like reaction when exposing the skin to sunlight or bright indoor light), a potential side effect in anyone undergoing PDT.¹

If, after reading this guide, you have further questions, be sure to discuss them with your healthcare professional.

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About Photodynamic Therapy

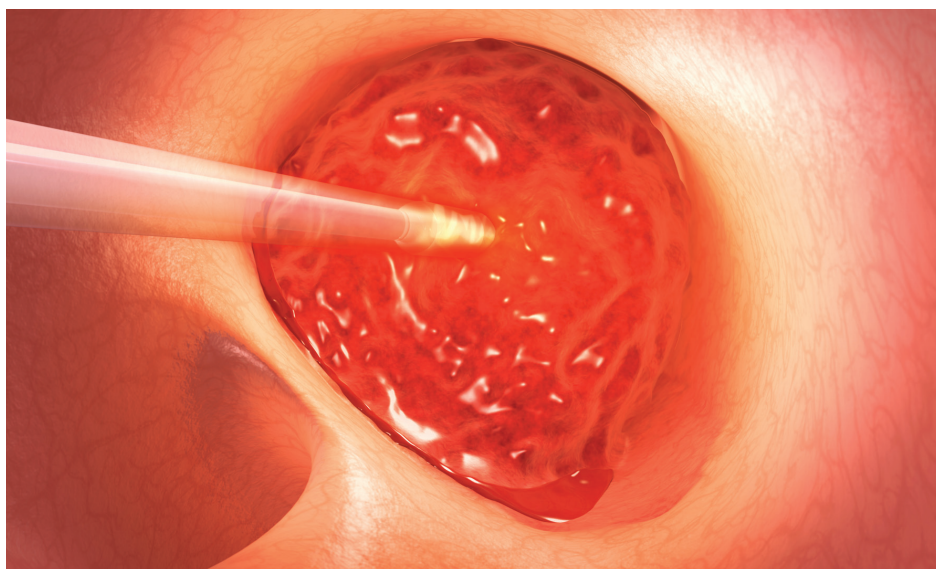
Photodynamic therapy happens in 2 stages.

Stage 1

A medicine called PHOTOFRIN® is injected into a vein in your arm.

Stage 2

The medicine is activated (switched on) by light from a laser. The laser is a source of light (red light) visible to your eyes. A laser light will be directed through fiber optic cables (similar to fishing lines) to deliver light to specific areas inside the body, such as the lungs or esophagus. This laser creates red light, not heat, so it will not burn.



About PHOTOFRIN®¹

Injection of PHOTOFRIN® (porfimer sodium) is the first in a 2-part treatment called photodynamic therapy (PDT). By itself, PHOTOFRIN® is inactive. However, when PHOTOFRIN® is put in the presence of a laser or another source of visible red light (light of a particular wavelength), it becomes active.

When injected, PHOTOFRIN® is particularly attracted to and remains in tissues containing abnormal cells.

When the red light is turned on, PHOTOFRIN® is activated and the abnormal cells are destroyed. In addition to directly killing abnormal cells, PDT with PHOTOFRIN® appears to shrink tumors by damaging blood vessels in the tumor and may activate the immune system to attack the tumor cells.

By delivering light to specific areas inside the body, such as the lungs or esophagus, damage to healthy tissue is usually minimal. However, in some cases, PDT can cause a sensation of burning, swelling, pain, and scarring in nearby healthy tissue.

PDT with PHOTOFRIN® will make your skin and eyes sensitive to bright light (photosensitive), meaning that you can experience effects similar to sunburn if you are exposed to light.

Bright light includes, but is not limited to:

- Direct sunlight
- Halogen lights and spotlights
- Unshaded light bulbs at close proximity
- Examination lights such as those used by your dentist or eye specialist
- Intense light such as those used in tanning salons, make-up lights, etc

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Before Treatment¹

Before leaving home, prepare the house for your return. Be sure the windows have blinds or shades to block out direct sunlight, and avoid direct sunlight from skylights.

What to bring to the hospital

Items from the patient kit including:

- Dark sunglasses with light transmittance of less than 4%
- Gloves
- Wide-brimmed hat
- Pocket card
- Bracelet

Also bring a bag with or wear light-colored clothing:

- Long-sleeved shirt or blouse
- Long pants or slacks
- Socks and shoes
- Scarf (must block light)

These are to protect your skin from bright light after you have had your injection.



During Treatment

PDT is usually performed as an outpatient procedure. There are 2 stages to your photodynamic therapy.

Stage 1 (Injection)

You will be given an injection into a vein in your arm of the photosensitizing drug PHOTOFRIN[®] 2 days before the procedure. This takes 3 to 5 minutes.¹ You will be photosensitive for at least 30 days following injection of PHOTOFRIN[®]. This means that your skin and eyes will be sensitive to bright lights (sunlight and bright indoor light).

Stage 2 (Light application)

Just prior to the procedure, you may be given a sedative and/or a local or general anesthetic, so you should feel little or no discomfort. These medicines may make you feel sleepy. However, patients are often awake while PDT with PHOTOFRIN[®] is administered.^{2,3}

Your doctor will direct the laser light through a fiber optic endoscope, a flexible tube that is placed down the throat. Forty to 50 hours after the PHOTOFRIN[®] injection, light from a laser will activate the drug within the lung or esophageal abnormal cells and destroy them. Light application may be repeated if needed. This is usually done 96 to 120 hours after a PHOTOFRIN[®] injection.¹

Your doctor will continue regular checkups of your condition. PDT with PHOTOFRIN[®] may be repeated and may be used with other therapies such as radiation, surgery, or chemotherapy.

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After Treatment¹

You will be provided with a patient kit that will include the following items:

- Dark sunglasses with light transmittance of less than 4%
- Gloves
- Wide-brimmed hat
- Pocket card
- Bracelet

All patients who have PHOTOFRIN[®] treatment will become more sensitive to light (photosensitive).

- Phototoxic reactions, such as redness or blistering on your skin, are similar to having sunburn. Most of the time this will just cause discomfort, but it is possible to get severe reactions that require hospital treatment
- To prevent any phototoxic reactions, you must avoid exposure to direct sunlight outside and bright indoor light for at least 30 days after receiving the PHOTOFRIN[®] injection
- Liver or renal impairment will likely prolong the elimination of PHOTOFRIN[®]. Hence, the period requiring precautionary measures for photosensitivity may be longer than 90 days
- **Talk to your doctor right away** if you are exposed to direct sunlight or bright indoor light without protection or if your skin becomes red or blistered at any time after your treatment



After Treatment¹

How to prevent a phototoxic reaction

You must protect your skin and eyes from sunlight and bright indoor light for at least 30 days after having PHOTOFRIN[®] and light treatment or until your skin test is negative (see skin testing on page 9). In patients with mild to moderate hepatic impairment, phototoxicity can last during 90 days or even more.

- Sunscreens bought from a drugstore or supermarket that protect you from ultraviolet (UV) light will not protect your skin from visible light. This is because PHOTOFRIN[®] makes you sensitive to visible light that is usually safe for humans
- Keep the curtains closed in your house during the day for the first 30 days. Afterwards, keep the curtains closed in your house if it is a sunny day or until your skin test is negative
- If you go out during daylight hours, do not leave any part of your body unprotected. Do this by wearing protective clothing (long-sleeved shirts and slacks [preferably tightly knit and light-colored]), socks, shoes, a wide-brimmed hat, scarf, and gloves. Try to save as many of your outdoor daily activities until dusk or the evening (whenever possible)
- You must also protect your eyes with dark sunglasses. You must do this even on cloudy days and while in a car or other vehicle. Please, be aware that these sunglasses are very dark and may impact your ability to drive and use machines
- You must keep away from bright indoor light such as dental lamps, operating room lamps, neon lights, and light bulbs that do not have a shade. However, you can still watch television or use a computer screen
- **Avoid "helmet"-type hair dryers** (found in hair salons), as they may cause a sunburn-type reaction. Handheld hair dryers on low settings are a safer option

You must not stay in a darkened room. After 30 days, you can have your curtains open if it is a dull, cloudy day. You can have lights on inside your house, as long as they have a shade. This will help speed up the natural process of the medicine losing its activity.

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After Treatment¹

How to test your skin for phototoxicity reaction

Before exposing your skin to bright light, you should test your skin to see if it is still sensitive to sunlight. Beginning 30 days after PHOTOFRIN[®] injection, you should start testing your skin:

- Cut a 2-inch hole in a paper bag and put your hand in the bag
- Expose this small area to sunlight for 10 minutes
- The next day, check your skin for a reaction
 - If you do not get a red mark, swelling or blisters, you can slowly return to your normal outdoor activities. However, try not to go outdoors during the middle of the day when the sun is brightest
 - If you do get a red mark, swelling or blisters, you should keep protecting yourself from the sun for 2 more weeks. Make sure that you expose your skin to ambient indoor light to speed up removal of the medicine from your skin. Then do the skin test again. You may have to use protective measures up to 90 days after PHOTOFRIN[®] injection



If you later go on vacation where there is more sunshine, do the skin test again. This is very important if some areas of skin have not been exposed to sunlight since your PHOTOFRIN[®] treatment.

Other Common Side Effects¹

Other common side effects of PHOTOFRIN[®], occurring in more than 10% of patients, include the following:

Treatment of the lung

When cancer obstructs (or blocks) the airway:

Shortness of breath, coughing with or without small amounts of blood, fever, pneumonia (infection of the lungs).

When cancer slightly invades surrounding tissues:

Fluid leaking out of blood vessels into nearby tissue, obstruction or mucus plug, swelling of tissue due to large fluid volume, stricture (narrowing) of the main airway leading to lungs.

Treatment of the esophagus

Anemia, fluid around the lungs, fever, constipation, nausea, chest pain, pain, abdominal pain, shortness of breath, pneumonia, vomiting, difficulty sleeping, back pain, inflammation of the throat.

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Other Possible Side Effects¹

Other potential side effects of PHOTOFRIN[®], occurring in 10% or less of patients, include the following:

Treatment of the lung

When cancer obstructs (or blocks) the airway:

Constipation, pain in the chest, pain (general), swelling of the tissues in the lower limbs due to large fluid volume, difficulty speaking, difficulty sleeping, anxiety, bronchitis, productive cough, difficulty breathing, fluid around the lungs, blood clot in the lung, blockage of the main artery of the lung or one of its branches, destruction of lung tissue due to infection, cardiac failure, bacterial infection of the blood, stroke.

When cancer slightly invades surrounding tissues:

Ulcers leading to the main airways of the lungs, cough, shortness of breath, inflammation of the digestive tract lining, life-threatening shortness of breath, narrowing of the main airway to the lungs that requires stent placement, coughing up life-threatening amounts of blood.

Other Possible Side Effects¹

Treatment of the esophagus

Abnormal heart rhythm, cardiac failure, faster than normal heart rate, difficulty swallowing, swelling of tissue of the esophagus due to large fluid volume, vomiting blood, indigestion, esophageal narrowing, diarrhea, inflammation of the esophagus, belching, blood in stool, swelling of tissue in the lower limbs due to large fluid volume, weakness, chest pain below the breastbone, swelling of tissue due to large fluid volume (general), fungal infection, urinary tract infection, post-procedural complication, weight loss, loss of appetite, dehydration, bleeding tumor, confusion, anxiety, difficulty breathing, cough, abnormal connection between the esophagus and windpipe, low blood pressure, high blood pressure, hole in the esophagus, stomach ulcer, blockage of the intestine due to paralysis of intestinal muscles, yellowing of the skin, inflammation of abdominal lining, bacterial infection of the blood, chest pain, slow heart rate, heart attack, various abnormal heart rhythms, fast heart rate, bronchitis, abnormal contraction of main airway leading to lungs, fluid build-up in the windpipe and voice box, inflammation of lung tissue, bleeding from the lungs, fluid build-up in the lungs, respiratory failure, abnormal high-pitched breathing sound, inflammation of the middle section of the chest cavity, abnormal vision, double-vision, eye pain and excessive eye sensitivity to light.

You are encouraged to report negative side effects of prescription drugs to Pinnacle Biologics, Inc. or the FDA. Call Pinnacle Biologics, Inc. at **1.847.283.7690**, visit <http://www.fda.gov/medwatch/> or call **1-800-FDA-1088**.

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Frequently Asked Questions

What is photodynamic therapy?

Photodynamic therapy, a treatment now being used in patients with certain types of lung and esophageal cancers, uses a combination of a photoactive drug (a drug that is activated by light) and red light from a laser. Both work to allow the doctor to specifically target and destroy abnormal cells while limiting damage to surrounding healthy tissue.¹

How does photodynamic therapy work against certain types of lung and esophageal cancers?

First, an injection of the photoactive drug PHOTOFRIN® (porfimer sodium) is given. PHOTOFRIN® will be absorbed by body tissues, including abnormal cells in most cases.¹

Over the next couple of days, the drug will largely be eliminated from most healthy tissue. However, it will remain in abnormal cells and certain other organs.¹

Approximately 40 to 50 hours after the PHOTOFRIN® injection, light from a laser will be directed at the abnormal cells. The application of light takes approximately 5 to 40 minutes depending on the amount of tumor the doctor wants to treat. For many patients the entire procedure takes under 1 hour. The light will activate the drug present within those abnormal cells and destroy them. In addition to killing abnormal cells, PDT with PHOTOFRIN® appears to shrink tumors by damaging blood vessels in the tumor and by activating the immune system to attack the tumor cells.¹

Because PHOTOFRIN® is retained to a greater degree by abnormal cells than by healthy cells, most of the healthy tissue surrounding the treated area will not be affected.¹



Frequently Asked Questions

Why can't I just take the drug?

Neither the drug nor the red light alone can destroy the abnormal cells; they must be used in combination. The drug must be activated by the red light before it can destroy the abnormal cells.¹

Does the laser light burn?

Low-power light from a laser is used, which is not the kind that is used for cutting in surgery. The light used in photodynamic therapy is nonthermal, meaning it does not burn.¹

How does the doctor administer the laser light?

The doctor will direct the light to its target through a fiber optic. Fiber optics that are specially designed to conduct laser light are thin, flexible, transparent strands, similar to fishing lines.

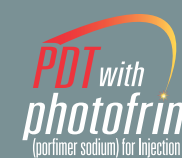
In treating esophageal cancer, the fiber optic is passed down the throat through an endoscope, a flexible tube.

In treating lung cancer, the fiber optic is passed through a bronchoscope, a tubular illuminated instrument used for inspecting or passing instruments into the lung airways.

Is the procedure painful?

With this procedure, a sedative is given along with local or general anesthesia, so you should feel little or no discomfort during the procedure.^{2,3} Local swelling and inflammation in and around the treated area may cause physical discomfort in that area after the treatment.¹

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Frequently Asked Questions

What precautions should I take to prevent a photosensitivity reaction?

You must be careful for at least 30 days after your injection to avoid bright indoor lights and direct sunlight. Some patients may remain photosensitive for up to 90 days. However, you must not limit yourself to dark rooms both in the hospital or once you are home. In fact, it is important to get some indoor light, because low levels of light will help break down the drug in your skin and make you less photosensitive.¹

The lighting in your home should not be a problem, but do stay away from direct sunlight, skylights, or undraped windows. Most indoor activities are fine including watching television or going to the movies.¹

When reading, do not expose your skin to the light from a reading lamp and keep your skin covered.¹

If at all possible, wait until sundown to do daily chores like shopping. If you go out during daylight hours, you must cover as much skin as possible. That means wearing a long-sleeved shirt, slacks, gloves, socks, shoes, and a wide-brimmed hat. Wear tightly woven, light-colored fabrics, if possible. You should also protect your eyes by wearing dark sunglasses with less than 4% white light transmittance. It is important for you to wear protective clothing and sunglasses even on cloudy days and while in a car.¹

For at least 30 days after the injection, stay away from bright examination lights, such as those found in a dentist's office, and helmet-type hair dryers like those found in hair salons, as they can cause skin burns. Handheld hair dryers at low settings are a safer option.¹

Frequently Asked Questions

Will sunscreens protect me from photosensitivity?

No. Sunscreens will not protect against photosensitivity, no matter how high the SPF, because sunscreens protect against ultraviolet (UV) light. Photoactivation is caused by visible light, not UV light, which is invisible.¹

The duration of photosensitivity differs from person to person. After the first 30 days you should do a test by exposing a small portion of skin, maybe the back of your hand or arm, to sunlight. Avoid using your face to test for photosensitivity.¹ One way is to cut a hole (about 2 inches) in a paper bag that you can put your hand into. Expose the unprotected patch to sunlight for 10 minutes. If a photosensitivity reaction (swelling, redness, or blistering) occurs within 24 hours of exposure, continue to protect yourself from the sun for another 2 weeks before re-testing. If no reaction occurs within 24 hours of exposure, you may gradually increase your exposure to sunlight.¹

Continue to watch for any reaction as some patients may remain photosensitive for 90 days or more. Limit your time outdoors between 11 AM and 2 PM, when the sun is strongest. Do not limit yourself to dark rooms in your home as it is important to get some indoor light to help break down the drug in your skin faster.¹

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Frequently Asked Questions

How will I know if I have had a photosensitive reaction and what should I do?

A photosensitivity reaction will look like a bad sunburn. Your skin will appear red and swollen. Just as with a sunburn, there may be some blistering. If you see that you have experienced a reaction, call your doctor at once. Your doctor will be the best guide as to how to treat your reaction.¹

References: 1. PHOTOFRIN [package insert]. Bannockburn, IL: Pinnacle Biologics Inc; 2011. 2. Heier SK. Photodynamic therapy for esophageal malignancies. In: Barkin JS, O'Phelan CA, eds. *Advanced Therapeutic Endoscopy*. 2nd ed. New York, NY: Raven Press; 1994;57-65. 3. Lightdale CJ, Heier SK, Marcon NE, et al. Photodynamic therapy with porfimer sodium versus thermal ablation therapy with Nd:YAG laser for palliation of esophageal cancer: a multicenter randomized trial. *Gastrointest Endosc*. 1995;42(6):507-512.



PHOTOFRIN® Important Safety Information¹

What does PHOTOFRIN® treat?

PHOTOFRIN® is approved for:

- Relieving symptoms of esophageal cancer when the cancer blocks the esophagus or when the cancer cannot be treated with laser alone
- Relieving symptoms and reducing obstruction of non-small-cell lung cancer in patients in whom the cancer obstructs (or blocks) the airway
- Treating non-small-cell lung cancer that slightly invades surrounding tissues in patients for whom usual treatments are not appropriate
- Removal of abnormal, precancerous cells (high-grade dysplasia) in Barrett's esophagus patients who do not undergo surgical removal of the esophagus

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PHOTOFRIN® Important Safety Information¹

Who should not take PHOTOFRIN®?

PHOTOFRIN® is not for everyone. PHOTOFRIN® should not be used in patients with*:

- Certain rare blood disorders such as porphyria
- An abnormal connection (fistula) between the esophagus and airways leading to the lungs
- Tumor extending into a major blood vessel
- Life-threatening breathing failure that requires emergency treatment
- Enlarged veins in the stomach or esophagus or ulcers in the esophagus

*Ask your doctor if PHOTOFRIN® is right for you.

PHOTOFRIN® Important Safety Information¹

What should I be aware of while taking PHOTOFRIN®?

- Fistula (an abnormal connection) can occur if esophageal tumor is eroding into the main airway leading to the lungs or one of its branches
- Bleeding can occur if you have enlarged veins in your esophagus
- Some patients who receive PHOTOFRIN® treatment are at high risk for coughing up life-threatening amounts of blood
- If you are being treated for high-grade dysplasia in Barrett's esophagus, biopsy of your esophagus will be performed every 3 months and checked by your doctor until 4 consecutive biopsies are negative for high-grade dysplasia
- Extreme caution should be taken when used for tumors in locations where treatment-induced inflammation could block the main airway, leading to life-threatening difficulty breathing
- If you require radiotherapy after treatment with PHOTOFRIN®, the radiotherapy should not be started until 2-4 weeks after your PHOTOFRIN® treatment
- Notify your doctor if you experience chest pain after treatment with PHOTOFRIN®. Your doctor may prescribe medication to help alleviate the pain
- Narrowing of the esophagus occurs frequently after treatment of high-grade dysplasia in Barrett's esophagus
- If you have liver or kidney problems you may be photosensitive for longer
- Precautionary measures to protect skin and eyes from sunlight and bright indoor light should be followed for more than 90 days

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Pinnacle Biologics, Inc.
2801 Lakeside Dr - Suite 209
Bannockburn, IL 60015
P: 1.847.283.7690
F: 1.847.283.7695
PinnacleBiologics.com

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