

Patient Guide

Understanding and preparing for photodynamic therapy (PDT)
with PHOTOFRIN[®] (porfimer sodium) for Injection



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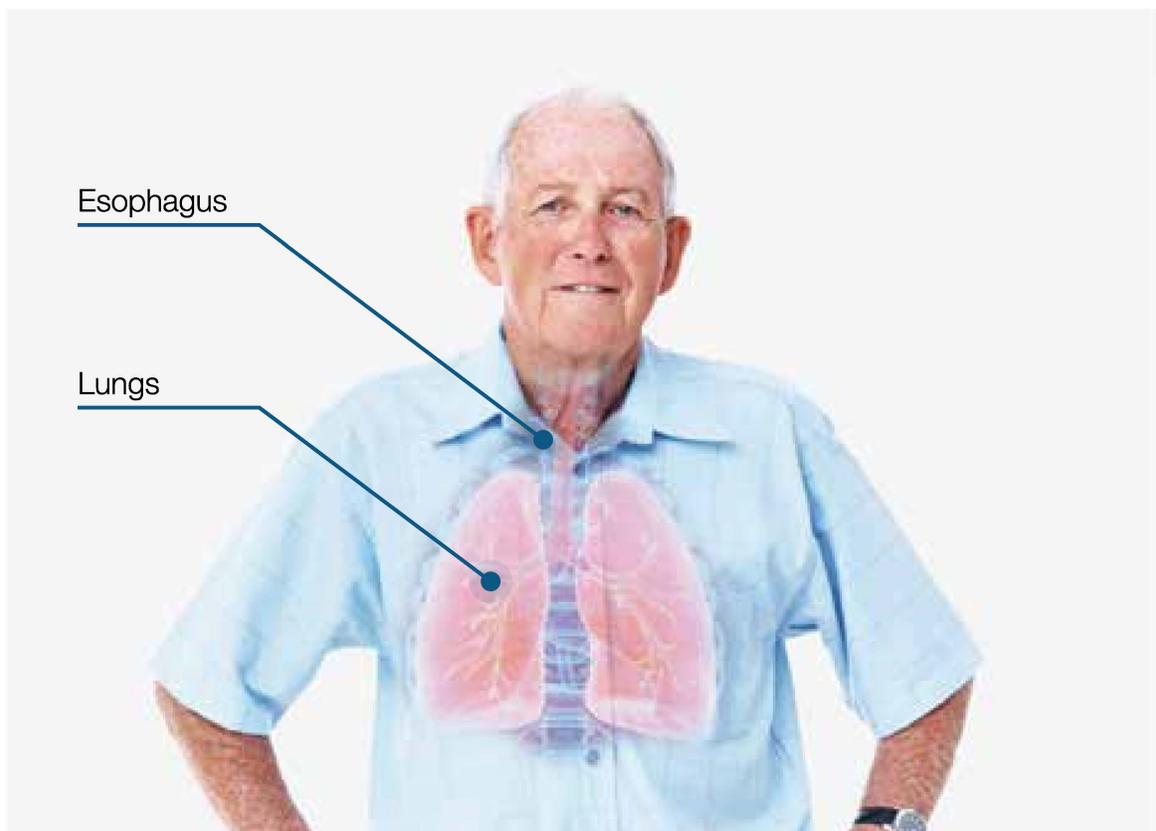
Welcome to PDT with PHOTOFRIN® (porfimer sodium) for Injection

Your healthcare professional (HCP) has given you this booklet because together you have decided that a treatment known as photodynamic therapy (PDT) is right for you. Your clinician should have reviewed most of this information with you. Please refer to this book for answers to questions you may have and feel free to take notes as you prepare for treatment.

PDT with PHOTOFRIN is an FDA-approved therapy, and its known side effects have been documented in the prescribing information for Photofrin (porfimer sodium) for Injection.

Please read this guide. If you have further questions, be sure to discuss them with your health care professional.

About your therapy



Photodynamic therapy, or PDT as it is often called, is a form of treatment for certain kinds of cancer. PDT combines a drug, a photosensitizing agent called PHOTOFRIN with a specific type of light to selectively kill cancer cells.

PDT with PHOTOFRIN is approved to treat a type of lung cancer known as non-small cell lung cancer. PDT with PHOTOFRIN may help to relieve symptoms if cancer is partially obstructing or completely blocking the airway, helping you breathe and feel better.

For patients with esophageal cancer PDT with PHOTOFRIN (porfimer sodium) for Injection may help to relieve the symptoms of cancer blocking the esophagus, and is also indicated for the removal of abnormal, precancerous cells in patients with a condition known as Barrett's esophagus.



Please see Important Safety Information on pages 15 and 16 and full US Prescribing Information enclosed.

Photodynamic therapy is a 2-step process

— Step 1

The medicine that makes cancer cells sensitive to specific light (a photosensitizing agent), PHOTOFRIN[®], is administered into your vein 2 days before your PDT light-application procedure.

— Step 2

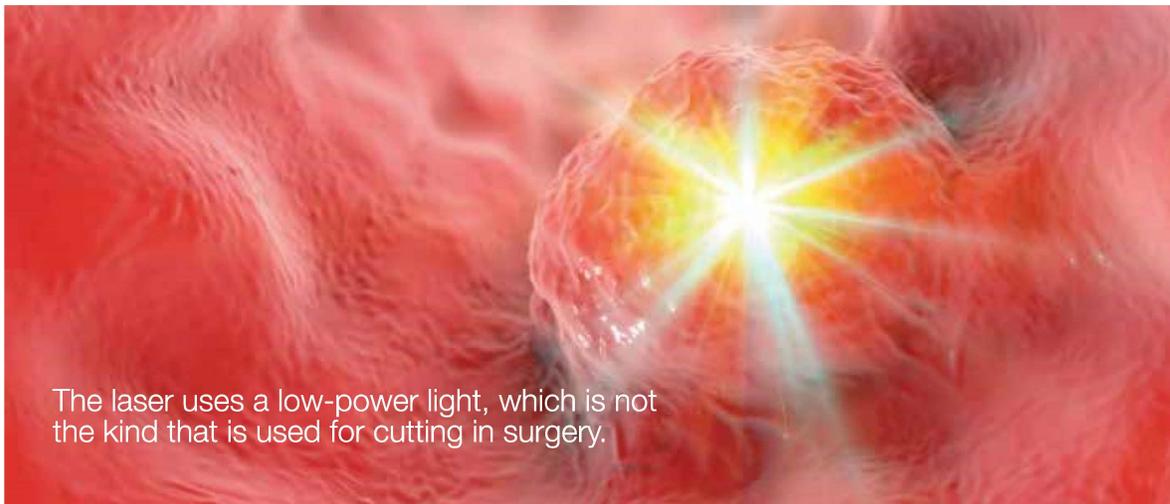
This is the light-application procedure, the part of the PDT light-application process in which the drug is activated by the red non-thermal laser light.



Your doctor will direct a very small diameter fiber optic through an endoscope into your lungs or esophagus. The light is delivered through the fiber optic. The light coming out from the laser is red, is not hot, and will not burn.

PHOTOFRIN[®] stays longer in cancerous and precancerous cells than in healthy tissue. It can take **40 to 50 hours** for most of the PHOTOFRIN[®] to clear from healthy tissues.

The light will activate the PHOTOFRIN[®] (porfimer sodium) for Injection within your cancerous or precancerous cells to help destroy them.



PDT with PHOTOFRIN causes cell damage and also decreases the blood flow to the tumor cells, causing them to die. This light application may be repeated, if necessary, **96 to 120 hours** after the PHOTOFRIN administration. Your skin will be sensitive to sunlight and bright indoor light for **at least 30 days** after you receive the Photofrin. This means that your skin and your eyes will need to be protected. Be sure to read the information about photosensitivity and how to protect yourself in the following pages.

Because PDT delivers light to specific areas inside the body (like the cancerous areas of the lung or esophagus), the damage to healthy tissue is usually minimal. However, in some cases, post procedure PDT can cause a burning sensation, swelling, pain, and scarring in nearby healthy tissue.

Why can't I just take the drug?

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

Common side effects of PDT with PHOTOFRIN® (porfimer sodium) for Injection

While all patients will be photosensitive after PHOTOFRIN administration, only some patients will have photosensitivity reactions, which can be an abnormally strong sunburn-like reaction to sunlight or bright indoor light. There are important steps that you must take to manage photosensitivity as soon as you receive your PHOTOFRIN.

The following list shows you other common side effects that may occur with PHOTOFRIN.

Esophageal Cancer

Photosensitivity reaction, 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.

Obstructing Endobronchial Cancer

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

Superficial Endobronchial Tumors

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

High-Grade Dysplasia in Barrett's Esophagus

Photosensitivity reaction, stricture (narrowing) of the throat, vomiting, chest pain, nausea, fever, constipation, difficulty swallowing, abdominal pain, fluid around the lungs, dehydration.



Managing photosensitivity during and after PDT therapy with PHOTOFRIN[®] (porfimer sodium) for Injection

Use your patient kit and these instructions to keep your skin protected from photosensitive reactions.

Understanding photosensitivity

The drug portion of your therapy, PHOTOFRIN® (porfimer sodium) for Injection, is a photosensitizing agent. It only works when exposed to light, like the red-light application step of your therapy. However, your skin and eyes will be sensitive to any bright light once you receive your Photofrin. This means you will be photosensitive and can get a sunburn-like reaction from any exposure to bright light, including:

-  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 lights, such as those used in tanning salons, make-up lights, etc

Photosensitivity may seem overwhelming, but it can be managed if you are careful. You have already received the first protective items that you will need in this kit.

Dress appropriately

When you go to the hospital for your Photofrin, you must be prepared for photosensitivity when you leave. With the contents of your patient kit, plus a few protective clothing items from home, this should help you be prepared to avoid a severe photosensitivity reaction.

 <p>Protective hat to shade your face and eyes</p> <p>IN YOUR KIT</p> <p>1</p>	 <p>Dark sunglasses to protect your eyes</p> <p>IN YOUR KIT</p> <p>2</p>
 <p>Gloves to protect your hands</p> <p>IN YOUR KIT</p> <p>3</p>	 <p>Pocket card, bracelet to identify you as photosensitive</p> <p>IN YOUR KIT</p> <p>4</p>
 <p>Light-colored scarf to cover your neck</p> <p>5</p>	 <p>Long-sleeved shirt to protect your arms</p> <p>6</p>
 <p>Long pants to protect your legs</p> <p>7</p>	 <p>Socks and shoes to make sure your feet are not exposed</p> <p>8</p>

Items 1–4 are included in your kit.

Be sure to cover up.
And remember, you will be photosensitive even indoors.

How will I know if I have a photosensitivity reaction?

A photosensitivity reaction will look like a bad sunburn. Your skin will appear red and swollen, and there may be some blistering. If you experience such a reaction, call your doctor at once.

Prevent problems from photosensitivity



Follow these instructions to prevent a photosensitivity reaction.

- Keep away from **bright indoor light** such as neon lights or bulbs that do not have a shade. Inform your doctors that you are photosensitive and need to stay away from bright lights that are sometimes used by dentists or in operating rooms. You can still watch television or look at a computer screen, but do take care while reading that you don't expose bare skin directly to the lamp light. Exposure to **ambient indoor light** is not a problem, and may speed up the removal of the medicine in your skin.
- If you go out in the daylight, do not leave any part of your body unprotected. Wear clothing as described on pages 10 and 11 to protect every part of your body. It's a good idea to try and save as many of your outdoor daily activities until dusk or after dark, if possible.
- Protect your eyes with dark sunglasses—even on a cloudy day or while inside a car or bus.

Despite all these precautions, you must not stay completely in the dark! Exposure to low levels of indoor light helps break down the drug in your skin and makes you less photosensitive. Please open the curtains on cloudy days until your skin test is negative.

Can I wear sunscreen to protect me from photosensitivity?

No. Sunscreens protect against ultraviolet (invisible) light, while photoactivation is caused by visible light. So, even the highest SPF won't protect you—you must keep your skin physically covered.

Testing your skin for photosensitivity

Four weeks after your Photofrin administration, you should test if your skin is ready for bright outdoor light. This is easy to do.



- 1.** Cut a 2-inch hole in a paper bag, then put your hand in the bag
- 2.** Rest your hand in the sunlight for a maximum of 10 minutes (keep your arm and the rest of your body covered)
- 3.** The next day, check your skin for a reaction

- A red mark, swelling, or blisters means you are still photosensitive. Keep protecting yourself from the sun for 2 more weeks, making sure you expose your skin to ambient indoor light to speed up the removal of the medicine from the skin. After 2 weeks, do the skin test again. You may have to use protective measures for up to 90 days after PHOTOFRIN® (porfimer sodium) for Injection.
- If your skin is unmarked, you can slowly return to your normal outdoor activities. However, try to avoid the outdoors during the middle of the day, when the sun is brightest. Initially avoid long periods of skin exposure to direct sunlight.
- If you later visit a place 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® (porfimer sodium) for Injection treatment.



Important Safety Information About PHOTOFRIN® (porfimer sodium) for Injection

PHOTOFRIN® should not be used in patients with porphyria, existing tracheoesophageal or bronchoesophageal fistula, tumors eroding into a major blood vessel, emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection of PHOTOFRIN® and laser light treatment, and esophageal or gastric varices or esophageal ulcers >1 cm in diameter.

Important Warnings and Precautions using PHOTOFRIN® include:

Gastroesophageal Fistula and Perforation: Do not initiate PHOTOFRIN with photodynamic therapy (PDT) in patients with esophageal tumors eroding into the trachea or bronchial tree or bronchial wall.

Pulmonary and Gastroesophageal Hemorrhage: Assess patients for tumors eroding into a pulmonary blood vessel and esophageal varices. Do not administer light directly to an area with esophageal varices.

High-Grade Dysplasia (HGD) in Barrett's Esophagus (BE): After treatment of HGD in BE, conduct endoscopic biopsy surveillance every 3 months, until 4 consecutive negative evaluations for HGD have been recorded.

Photosensitivity and Ocular Photosensitivity: Observe precautions to avoid exposure of skin and eyes to direct sunlight or bright indoor light for at least 30 days. Instruct patients when outdoors to wear dark sunglasses which have an average light transmittance of <4% for at least 30 days and until ocular sensitivity resolves.

Use Before or After Radiotherapy: Allow 2-4 weeks between PDT and subsequent radiotherapy.

Chest Pain: Substernal chest pain can occur.

Airway Obstruction and Respiratory Distress: Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Monitor patients closely between the laser light therapy and the mandatory debridement bronchoscopy for any evidence of respiratory distress.

Esophageal Strictures: Esophageal strictures can occur.

Hepatic and Renal Impairment: Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity.

Thromboembolism: Thromboembolic events can occur.

Embryo-Fetal Toxicity: May cause embryo-fetal toxicity. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

MOST COMMON ADVERSE REACTIONS reported during clinical trials (>10% of patients) are:

Esophageal Cancer: Anemia, pleural effusion, pyrexia, constipation, nausea, chest pain, pain, abdominal pain, dyspnea, photosensitivity reaction, pneumonia, vomiting, insomnia, back pain, pharyngitis.

Obstructing Endobronchial Cancer: Dyspnea, photosensitivity reaction, hemoptysis, pyrexia, cough, pneumonia.

Superficial Endobronchial Tumors: Exudate, photosensitivity reaction, bronchial obstruction, edema, bronchostenosis.

High-Grade Dysplasia in Barrett's Esophagus: Photosensitivity reaction, esophageal stenosis, vomiting, chest pain, nausea, pyrexia, constipation, dysphagia, abdominal pain, pleural effusion, dehydration.

Other photosensitizing agents may increase the risk of photosensitivity reaction. Because of the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with PHOTOFRIN and for 5 months after the last dose.

Please see accompanying full Prescribing Information for PHOTOFRIN® (porfimer sodium) for Injection at: www.photofrin.com

For more information about PHOTOFRIN®, or if there are any questions regarding the information provided, visit www.photofrin.com or please contact the Medical Information Department at **1-866-248-2039**. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

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