



BRIGHT DAYS AHEAD

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

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

 **PDT WITH
PHOTOFRIN®**
(porfimer sodium) for Injection
Light up the possibilities

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 doctor should have reviewed most of the information with you, but you can refer to this book for answers to your questions and there are also pages to write notes and questions as you prepare for treatment.

PDT with PHOTOFRIN is a proven therapy, and its known side effects have been documented. There are steps you should take to minimize photosensitivity.

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

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, called a photosensitizing agent—PHOTOFRIN—with a specific type of light to kill cancer cells.

PDT with PHOTOFRIN is approved to treat a type of lung cancer known as non-small cell lung cancer in patients who can't benefit from a traditional treatment like surgery and radiotherapy. PDT with PHOTOFRIN can relieve symptoms if cancer is obstructing or blocking your airway, helping you breathe and feel better.

For patients with esophageal (food pipe) cancer who can't be helped by laser treatments alone,

PDT with PHOTOFRIN® (porfimer sodium) for Injection can relieve the symptoms of cancer blocking the esophagus, making it easier for you to swallow. The therapy also is indicated for removal of abnormal, precancerous cells in patients with a condition known as Barrett's esophagus who do not undergo surgical removal of the esophagus.



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Photodynamic therapy is a 2-step process

PDT with PHOTOFRIN® (porfimer sodium) for Injection happens in 2 stages. **STEP 1** is the injection of the light-sensitizing drug. **STEP 2**, activation with light from a laser, is 2 days later. This is usually performed as an outpatient procedure. Let's look at these steps more closely.

STEP 1: The medicine that makes cancer cells sensitive to specific light (a photosensitizing agent), PHOTOFRIN, is injected into a vein in your arm 2 days before your PDT procedure. This takes about 3 to 5 minutes.

NOTE: PHOTOFRIN, by itself, is inactive.

STEP 2: This is the light-application step, the part of the process in which the drug is activated or turned on by light from a laser.

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Before your procedure, you may be given a sedative and/or a local or general anesthetic. This is to ensure you feel little or no discomfort. Patients may be awake while PDT with PHOTOFRIN is being performed.

Your doctor will direct the laser light using a *fiber optic endoscope*, which is a flexible tube that's similar to a fishing line and is placed down your throat. This is how the light is delivered to specific areas in your body, such as your lungs or esophagus. The light coming out from the laser is red, but it's not hot and will not burn. Remember, the light activates the medicine that was injected in you 2 days earlier. That's because it can take 40 to 50 hours for most of the PHOTOFRIN to clear from normal tissues. PHOTOFRIN stays longer in cancerous and precancerous cells than in normal tissue.

The light will activate the PHOTOFRIN® (porfimer sodium) for Injection within your cancerous or precancerous cells to help destroy them. PDT with PHOTOFRIN can help shrink tumors by causing the cell damage that can cause them to die or by decreasing the blood flow to the tumor cells causing them to die. This light application may be repeated, if necessary, 96 to 120 hours after a PHOTOFRIN injection.

Just as the abnormal, or cancerous, cells become photosensitive, you will also be sensitive to sunlight and bright indoor light for at least 30 days after you receive the injection. In some patients, photosensitivity can last 90 days or longer. 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.**

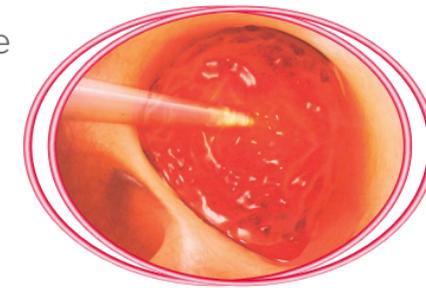
Because PDT delivers light to specific areas inside the body (like the cancerous areas of the lung

or esophagus), the damage to healthy tissue is usually minimal. However, in some cases, PDT can cause a burning sensation, swelling, pain, and scarring in nearby healthy tissue.

Read more about these side effects, and most importantly, photosensitivity, in the following pages.

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.



The laser uses a low-power light, which is not the kind that is used for cutting in surgery. It is nonthermal, meaning it doesn't burn.

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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 injection. The rest of this booklet is dedicated to these instructions. Please read them carefully.

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

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

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| 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 |

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 or call Concordia Laboratories Inc. at 1-866-248-2039.

Photosensitivity

As mentioned earlier, photosensitivity is the most common concern with PDT. Side effects from photosensitivity can be managed by properly protecting yourself from light, both indoors and out. The rest of this booklet focuses on how to do that. **Please read these pages carefully.**



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 stage of your therapy. However, your skin and eyes will be sensitive to *any* bright light once you receive your injection. In other words, you will be photosensitive, meaning you 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've already received the first things you'll need in this kit. Remember to bring them to the hospital when you receive your injection.

Dress for success

When you go to the hospital for your injection, you must be prepared for photosensitivity after you leave. With the contents of your patient kit, plus a few things from home, you'll be all set.

- 1 Wide-brimmed hat to shade your face and eyes
- 2 Dark sunglasses (light transmittance <4%) to protect your eyes
- 3 Gloves to protect your hands

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- 4 Pocket card, bracelet to identify you as a person with photosensitivity
- 5 Light-colored scarf to cover your neck
- 6 Light-colored, long-sleeved top to protect your arms
- 7 Light-colored long pants to protect your legs
- 8 Socks and shoes to make sure no part of your feet is exposed

These items are included in your patient kit

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



How will I know if I've had a photosensitive reaction?

A photosensitivity reaction, also called phototoxicity, 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

Once you've had your injection, you must be careful to prevent a phototoxic reaction for at least 30 days, or until your skin test is negative. (Instructions for performing a skin test are on page 14.) If you have mild-to-moderate liver impairment, phototoxicity can last 90 days or even longer.

Follow these instructions to prevent a phototoxic 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

- 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. Also, the proper sunglasses, like those in your kit, are very dark. Wearing them may affect your ability to drive or use machines
- Do not sit under a bonnet hair dryer (like at the salon), as the sustained heat can cause a sunburn-type reaction. Instead, use a blow dryer on a low setting

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.**

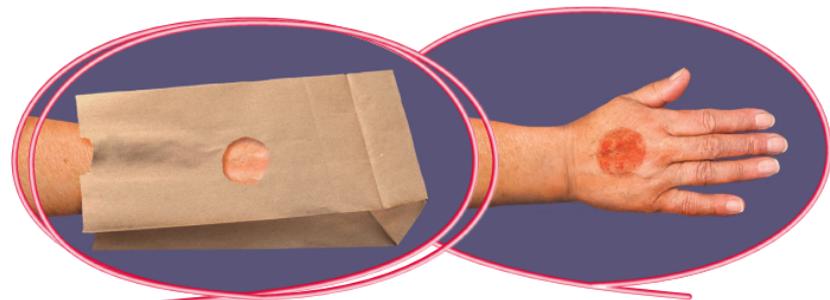
Can I wear sunscreen to protect me from photosensitivity?

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

Two weeks after treatment, you should test if your skin is ready for bright 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 10 minutes (keep your arm 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

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.



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PHOTOFRIN® (porfimer sodium) for Injection

Important Safety Information and Indication

Do not take PHOTOFRIN:

- If you have a rare disorder with a blood component called porphyria
- If you have an abnormal connection (fistula) between the esophagus and airways leading to the lungs
- If you have a tumor extending into a major blood vessel
- If you have life-threatening breathing failure due to an obstructing airway tumor that requires emergency treatment

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

- If you have enlarged veins in the stomach or esophagus or large ulcers in the esophagus

What should I tell my healthcare provider before taking PHOTOFRIN?

Before taking PHOTOFRIN, tell your healthcare provider about all your medical conditions, including if you are:

- Taking other medicines that are activated by light
- Taking other medicines during your photodynamic treatment with PHOTOFRIN
- If you are pregnant or are a nursing mother

What is the most important information I should know about PHOTOFRIN?

- Sensitivity or allergic reaction to light can be expected; eye sensitivity is possible. This reaction is called phototoxicity, which has a sunburn-like effect and may be severe. All patients receiving

PHOTOFRIN® (porfimer sodium) for Injection will be sensitive to light and must take precautions to avoid exposure of eyes and skin to direct sunlight or bright indoor light for at least 30 days, but it may be required for more than 90 days. The phototoxicity with PHOTOFRIN is unique since it is activated, not only by UV light, but also by light visible to your eyes that is usually safe for humans. Phototoxicity reactions with PHOTOFRIN can occur following the first exposure to direct sunlight or intense indoor light from within a few minutes to up to several hours after exposure; resulting skin damage can persist. After PHOTOFRIN administration, when outside wear protective clothing and dark sunglasses which let less than 4% white light through

- An abnormal connection (fistula) can occur if an esophageal tumor is eroding into the main airway leading to the lungs or into one of its branches

- Holes can develop through the wall of the organs in your digestive system where photodynamic therapy was applied (esophagus, stomach, small intestine, large bowel, rectum, gallbladder)
- Bleeding can occur if you have enlarged veins in your esophagus
- Some patients with treated lung cancer lesions are at high risk for coughing up life-threatening amounts of blood
- If you are being treated for pre-cancerous cells (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
- If you require radiotherapy after treatment with PHOTOFRIN, the radiotherapy should not be



started until 2-4 weeks after your PHOTOFRIN® (porfimer sodium) for Injection treatment

- You may experience chest pain or breathing difficulty. Notify your doctor if you experience chest pain or any other side effects after treatment with PHOTOFRIN. Your doctor may prescribe medication to help reduce the pain
- Photodynamic therapy for advanced lung cancer may block the main lung airway, leading to life-threatening difficulty breathing
- Narrowing of the esophagus occurs frequently after treatment of pre-cancerous cells (high-grade dysplasia) in Barrett's esophagus
- If you have liver or kidney problems you may need to take extra precautions regarding sensitivity to light and for a longer time period
- Blockage of blood vessels from pieces of a blood clot can happen after treatment with PHOTOFRIN

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

What are the possible side effects of PHOTOFRIN?

Sensitivity to light will occur in all patients. Allergic reaction to light may occur in all of the following indications:

- **For esophageal cancer (treatment of the esophagus):** anemia, accumulation of fluid in the lungs, fever, constipation, nausea, chest pain, general pain, stomach pain, difficulty breathing, pneumonia (infection of the lung), vomiting, difficulty sleeping, back pain, inflammation of the throat
- **For obstructing endobronchial cancer (when cancer blocks the lungs airways):** difficulty breathing, coughing with or without small amounts of blood, fever, coughing, pneumonia (infection of the lungs)
- **For superficial endobronchial tumors (when cancer slightly invades surrounding tissues):** fluid

leaking out of blood vessels into nearby tissue, blockage of lung airways, swelling of tissue due to large fluid volume, narrowing of the main airway leading to lungs

- **High-grade dysplasia (pre-cancerous cells) in Barrett's Esophagus (treatment of the esophagus):** narrowing of the esophagus, vomiting, chest pain, nausea, fever, constipation, difficulty or pain when swallowing, abdominal pain, accumulation of fluid in the lungs, dehydration

These are not all the possible side effects of PHOTOFRIN® (porfimer sodium) for Injection. 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 or call Concordia Laboratories Inc. at 1-866-248-2039.

Indication

PHOTOFRIN is used for:

- Relieving symptoms of esophageal cancer when the cancer blocks the esophagus or when the cancer cannot be treated by laser alone
- Treating non-small-cell lung cancer that slightly invades surrounding tissues when the other usual treatments are not appropriate
- Relieving symptoms and reducing obstruction of non-small-cell lung cancer in patients in whom the cancer blocks the lung airways
- Removal of abnormal, pre-cancerous cells (high-grade dysplasia) in Barrett's esophagus when there is no removal of the esophagus by surgery

Please see Full Prescribing Information.



Please see Important Safety Information and enclosed full Prescribing Information for PHOTOFRIN® (porfimer sodium) for Injection.

FOR MORE INFORMATION ABOUT PHOTOFRIN visit www.Photofrin.com or call Concordia Laboratories Inc. at 1-877-370-1142.

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See more at: <http://www.photofrin.com/healthcare-professional-home/#sthash.FinUvOe7.dpuf>.

If there are any questions regarding the information provided, please contact Concordia's Medical Information Department at 1-877-370-1142.

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