

PACKAGE LEAFLET: INFORMATION FOR THE USER

Photofrin 75 mg Powder for solution for injection

Porfimer sodium

Read all of this leaflet carefully before you have this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Photofrin is and what it is used for
2. Before you are given Photofrin
3. How Photofrin will be given
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1. What Photofrin is and what it is used for

What Photofrin is

Photofrin contains a medicine called porfimer sodium. It is used as part of a treatment called 'photodynamic therapy'. Porfimer sodium is similar to porphyrin-type substances that occur naturally in the blood, i.e., haemoglobin.

What Photofrin is used for

Photofrin is used to treat certain types of cancer:

- tumours in your lung called 'Non-small cell cancer' (endobronchial cancer) - these may block your wind pipe
- tumours in your food pipe (oesophageal cancer) - these may block your food pipe (oesophagus).

How Photofrin works

Photofrin works by killing abnormal cancer cells.

- The medicine is injected into your body and activated ('switched on') by a red laser light. In this leaflet we call this 'light treatment'.
- Using the medicine helps the laser to kill the abnormal cancer cells exactly where it is needed.
- Both the medicine and the light treatment are needed for the therapy to work. The combination of medicine and light treatment is called 'Photodynamic Therapy'.

2. Before you are given Photofrin

Do not have Photofrin if:

- you are allergic (hypersensitive) to porfimer sodium or any of the other ingredients of Photofrin (listed in Section 7)
- you are allergic (hypersensitive) to other ‘porphyrins’
- you have serious breathing problems caused by a large tumour blocking your airways
- you have ‘porphyria’ (a rare blood problem)
- you have an opening between your food pipe and your airways
- your cancer has gone into a major blood vessel
- you have serious liver or kidney problems.

Do not have Photofrin if any of the above apply to you. If you are not sure, talk to your doctor or nurse before having this medicine.

Take special care with Photofrin

Check with your doctor or nurse before having Photofrin if:

- you have liver or kidney problems
- you have ever had a serious lung or heart problem
- You have had radiotherapy in the last 2 to 4 weeks.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before having Photofrin.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you get without a prescription, such as herbal medicines. It is possible that some medicines will reduce the effectiveness of your Photofrin treatment or make the photosensitivity side effect worse.

Pregnancy and breast-feeding

- Do not have Photofrin when you are pregnant, unless your doctor thinks it is necessary.
- It is important not to get pregnant while having treatment with Photofrin. Use contraception while and for at least 90 days after having Photofrin.
- Do not breast-feed while having Photofrin.

Driving and using machines

- Photofrin itself is not likely to affect your ability to drive.
- During your light treatment, you may be given medicines to make you sleepy. Therefore do not drive or use tools or machines after your light treatment.

Things to prepare before you have Photofrin

- This medicine will make you sensitive to light (photosensitive) as soon as the injection has been given. See Section 4, for more information on photosensitivity.
- Before you go to have your Photofrin injection, check in your home that all light bulbs are covered with shades and that the curtains will keep out bright sunlight.
- Remember to take enough clothing with you to your appointment, so that all your skin will be covered. You will need a long-sleeved shirt, trousers, socks, shoes, gloves and a hat with a wide brim. You will also need dark sunglasses to protect your eyes.

3. How Photofrin will be given

Step 1) Photofrin injection

- Photofrin is given to you by a slow injection (3 to 5 minutes), into a vein in your arm.
- The doctor or nurse will give you this injection.
- The doctor will decide your dose. The usual dose is 2 mg for each kg of body weight.

Step 2) Light treatment

- 40 to 50 hours after your injection, you will have the light treatment. It is given later because by that time, the medicine will have left most of your body. It will mainly be left in the cells in your tumour and in your skin.
- You may be given a medicine to make you sleepy.
- You will also be given a local anaesthetic so that you feel little or no discomfort.
- The doctor will treat the tumour area with a red laser light (which is non-burning). This 'switches on' the medicine in the tumour.
- 2 days after the light treatment, the doctor may remove any of the dead tumour.
- 4 to 5 days after your Photofrin injection, the doctor may give you a second light treatment.

After the light treatment, you should only eat liquid food for a few days (in some cases up to 4 weeks).

How many injections will you have

After further tests, the doctor may decide to give you up to two more injections of Photofrin. Each injection will be at least 30 days apart.

What you should do if you miss the light treatment

Both the medicine and light treatment are needed for the therapy to work. If you miss your appointment for the light treatment, talk to your doctor straight away. Your doctor will decide how to go ahead with the treatment.

4. Photosensitivity

- All patients who have Photofrin will be photosensitive (sensitive to light).
- You must keep out of direct sunlight and bright indoor light for at least 30 days
- Photosensitive reactions are similar to having sunburn, such as redness, swelling, feeling hot, a burning sensation, itching or blisters on your skin.

How to prevent a photosensitivity 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:

- **Sunscreens that protect you from ultraviolet (UV) light will not protect your skin.** This is because Photofrin makes you sensitive to the red part of light (not the UV part of light).
- **Keep the curtains closed in your house if it is a sunny day.**
- **If you go out during daylight hours, cover as much skin as possible.** Do this by wearing a long-sleeved shirt, trousers, socks, shoes, gloves and a hat with a wide brim.
- **You must also protect your eyes with dark sunglasses.** You must do this even on cloudy days and while travelling in a vehicle.
- **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.
- **You do not need to stay in a darkened room.** 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.

If you have liver problems, you may be sensitive to light for more than 90 days and will need to keep protecting yourself.

Testing your skin

After 30 days, you should test your skin to see if it is still sensitive to sunlight:

- Cut a two inch hole in a paper bag and put it on your hand or elbow.
- 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 two more weeks. Then do the skin test again.
- If you go on holiday 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.

Reporting of side effects

- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. Other possible side effects

Like all medicines, Photofrin can cause other side effects, although not everybody gets them. If you notice any side effects, including side effects not listed in this leaflet, please tell your doctor or nurse immediately. The following side effects may happen:

All patients:

- swelling at the area of the tumour. This can last for several days and cause chest pain
- rashes. This could be a sign of an allergic reaction
- anaphylaxis, which is a very serious type of allergic reaction that can be life-threatening. Symptoms include very low blood pressure and difficulty breathing.
- problems with swallowing that may cause pain
- feeling or being sick.

You should only eat liquid food for a few days (in some cases up to 4 weeks) after the light treatment.

Patients with cancer of the wind pipe (endobronchial cancer):

Very common side effects (affects more than 1 in 10 people):

- coughing up blood
- high temperature (fever)
- swelling of the airways (bronchitis), cough, difficulty in breathing, lung infection (pneumonia).

Common side effects (affects less than 1 in 10 people):

- back pain, chest pain or general pain

- water/fluid retention producing a swollen body
- constipation, indigestion
- feeling nervous (anxiety), problems sleeping
- coughing up more phlegm (pronounced 'flem').

Uncommon side effects (affects less than 4 in 100 people)

- blood clots
- fluid in your chest, fluid or an abscess on your lungs.

Patients with cancer of the food pipe (oesophageal cancer):

Very common side effects (affects more than 1 in 10 people):

- general pain
- problems sleeping
- high temperature (fever)
- pain and swelling of the throat
- chest pain, difficulty in breathing
- a lower number of red cells in your blood (anaemia) due to blood loss. The risk of blood loss depends on the location and size of the cancer
- stomach pain, feeling or being sick, constipation
- fluid on your lungs, lung infection (pneumonia).

Common side effects (affects less than 1 in 10 people):

- back pain
- feeling confused, weak
- water/fluid retention producing a swollen body or hands and feet
- weight loss or loss of appetite, dehydration
- abnormal opening between the wind pipe and the food pipe
- infections including thrush, urine infection or infections through the whole body
- diarrhoea, indigestion, being sick with blood in it,
- build up of fluid in your food pipe, narrowing of the food pipe, bleeding of the tumour in your food pipe
- high blood pressure or low blood pressure
- uneven heartbeat, fast heart beat or your heart being unable to pump the blood properly (heart failure).

Uncommon side effects (affects less than 4 in 100 people)

- chest pain or heart attack
- slow heart beat
- difficulty in swallowing
- difficulty in breathing, a whistling sound when you breathe
- punctured food pipe, swelling of the food pipe
- swelling of the airways (bronchitis), narrowing of the airways
- swelling of the lungs, bleeding of the lungs
- yellowing of the skin or whites of your eyes (jaundice).
- stomach ulcer, blockage of the intestine, tummy pain or tenderness due to swelling
- change in your vision, double vision, eye pain, your eyes being more sensitive to light.

Postmarketing

The following side effects have been reported with porfimer sodium for some or all indications.

- lower number of red cells in your blood
- high white blood cell count
- uneven, abnormal or slow heart beat
- heart conduction system problems
- vision fatigue, cataract, red eyes
- difficulty swallowing, stomach ulcer, lesion in intestine, vomiting blood, dry lips, feeling sick, swelling of the mouth, painful swallowing, abnormal opening at the food pipe, pain in the food pipe, hole in the food pipe, narrowing of the food pipe, food pipe ulcer, food pipe inflammation, oral pain, inflammation of the pancreas, abnormal opening between the wind pipe and the food pipe, being sick
- swelling at the application site, fatigue/malaise, chest pain/discomfort, chills, swelling of the hands and feet, fever, swelling
- blood clots in your vessels
- allergic reaction
- lung infection
- airway injury, food pipe injury
- blood components disorder, abnormal vision
- dehydration, too much fluid in the body, low serum calcium levels in the blood
- dizziness, reduced sense of touch or sensation, fainting,
- bladder contraction, painful urination, too much fluid in kidneys, urgent urination, need to get up during the night to urinate, not able to urinate
- abnormal opening in the airways, airways bleeding, cough, shortness of breath, coughing up blood, hiccups, accumulation of fluids on your lungs, blood clots in your lung vessels
- rapid swelling, blister, dry skin, redness of the skin, swelling of the face, generalized skin redness, skin disease due to sunlight, sensitive to light, skin colour disorder, itching, blistering skin reaction due to sunlight, rash, rash generalized, skin burning sensation, sunburn, hives
- blood clots in your vessels, blockage of blood arteries, low blood pressure, inflammation of a vein

6. How to store Photofrin

The staff at the hospital will store this medicine. The storage details are:

- Store below 25°C.
- Keep the vial in the outer carton to protect it from light.
- After preparation, Photofrin should be used straight away (within 3 hours). Chemical and physical in-use stability has been demonstrated for 24 hours at 3°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 to 8°C.
- Do not use after the expiry date shown on the carton and vial.
- Keep out of reach and sight of children

7. Further information

What Photofrin contains

- The active substance is porfimer sodium. Each vial contains 75 mg of porfimer sodium.
- The other ingredients are hydrochloric acid and sodium hydroxide (to balance the pH level).

What Photofrin looks like and contents of the pack

Porfimer sodium is a reddish brown powder for solution for injection.
The medicine comes in a vial for single use.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

DELPHARM HUNINGUE SAS
26 Rue de la Chapelle
68330 HUNINGUE
FRANCE

This leaflet was last approved in 2018-07-27