

**FOSCAN** 4mg/ml  
Solution for Injection  
TEMOPORFIN

**READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**In this leaflet:**

1. What Foscan is and what it is used for.
2. Before you use Foscan.
3. How to use Foscan.
4. Possible side effects.
5. Storing Foscan.

**The name of your medicine is:**

Foscan 4 mg/ml Solution for Injection  
Temoporfin

- The active substance is temoporfin 4 mg/ml
- The other ingredients are ethanol anhydrous and propylene glycol.

**Marketing authorisation holder:**

biolitec pharma ltd.  
Edinburgh, EH14 4AP  
United Kingdom

**Manufacturer:**

biolitec pharma ltd.  
Breasclete  
Isle of Lewis, HS2 9ED,  
United Kingdom

**1. WHAT FOSCAN IS AND WHAT IT IS USED FOR**

Foscan is a porphyrin photosensitising medicine. It comes as a solution for injection and contains 4mg/ml temoporfin. You will be given Foscan by injection. To make Foscan work, you will be given treatment with laser light four days after your injection. This light allows Foscan to treat your head and neck cancer.

**2. BEFORE YOU USE FOSCAN**

**Do not use Foscan:**

- if you are hypersensitive (allergic) to temoporfin or ethanol or propylene glycol
- if you are hypersensitive (allergic) to porphyrins
- if you have porphyria, or any other disease that is made worse by light
- if the tumour being treated goes through a large blood vessel
- if you are going to have an operation in the next 30 days
- if you have an eye disease which needs examination with bright light in the next 30 days
- if you are already being treated with a photosensitising agent.

**Take special care with Foscan:**

Foscan will make you sensitive to light for about 15 days after your injection. This means that normal daylight or bright indoor lighting could give you skin burns. To stop this, you MUST follow carefully the instructions for gradual exposure to increasing light levels indoors over the first week and outdoor, shaded light the second week after treatment. Please speak to your doctor about this before you go home after being injected with Foscan. Sunscreen creams will not prevent this sensitivity. You will gradually become less sensitive to light. Normally, people are able to begin to return to normal outdoor lighting after 15 days.

You must not use UV sunbeds or sunbathe, or let an optician examine your eyes with bright lights, for 3 months after Foscan injection

**The table of instructions tells you what to do to prevent skin burns. You must follow these instructions carefully.**

Please ask your doctor, nurse or pharmacist if you are not sure about anything.

**Taking Foscan with food and drink:**

Your normal food and drink will not affect your treatment with Foscan.

**Pregnancy:**

You must avoid becoming pregnant for 3 months after Foscan treatment.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant.

**Breast-feeding:**

Do not breast feed for at least 1 month after Foscan injection.

**Driving and using machines:**

Treatment with Foscan will not directly affect your ability to drive or use machines. However, in the light conditions recommended for the first 15 days after Foscan injection, driving is not recommended, and it may not be practical to operate machinery.

**Important information about some of the ingredients of Foscan:**

**WARNING:** This product contains 40% by weight of ethanol. Each dose contains approximately 0.015g/kg body weight alcohol. Harmful for those suffering from liver disease, alcoholism, epilepsy, brain injury or disease, as well as for pregnant women and children. May modify or increase the effect of other medicines.

**Using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed by a doctor.

**3. HOW TO USE FOSCAN**

Your doctor or nurse will give you Foscan by injection into a vein. If necessary, your doctor or nurse may give you another injection at least 4 weeks later. Four days after your injection, your doctor will treat your cancer with laser light.

**If you are given more Foscan than you should:**

You may not be given the laser treatment. You may be sensitive to light for more than 15 days. You must follow carefully the instructions on preventing skin burns.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Foscan can have side effects.

Everyone who takes Foscan will become sensitive to light for about 15 days after injection. You **MUST** follow the instructions given to you to avoid sunlight and bright indoor light. These instructions are written in this leaflet. Your doctor will also tell you what to do. If you do not follow these instructions, you may get severe sunburn that leads to permanent scarring. You may also get blisters, skin redness, or skin darkening.

You may feel some pain or a burning sensation when Foscan is injected. There may be some irritation or skin damage where Foscan is injected, but this will not last long.

After the laser treatment, you may feel some pain. There may also be swelling, bleeding, ulcers and scarring around the treated area. These effects may make it difficult to eat and drink or may cause a stiff jaw. Some people may get an infection in the treated area.

Other effects may be vomiting, nausea, anaemia, giddiness, or constipation.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

**5. STORING FOSCAN**

Foscan will be stored at the hospital pharmacy  
Keep out of the reach and sight of children  
Do not store above 25°C  
Store in the original container  
Keep the container in the outer package.  
Do not use after the expiry date stated on the label.

**This leaflet was last approved on 07-2002.**

Time after Foscan Injection	What should I do to prevent burns?
<b>Day 1 (0-24 hours)</b>	Stay indoors in a darkened room. Keep the curtains drawn and use light bulbs of 60W or less. <b>Avoid exposure to direct sunlight.</b>
<b>Days 2 - 7</b>	You can gradually return to normal indoor lighting. Remember to <b>avoid direct sunlight coming through the window</b> or direct light from household appliances such as reading lamps. You may watch television.  You can go outdoors after dusk.  If it is absolutely necessary to go outdoors during the hours of daylight, you must be careful to <b>cover up all your skin including your face and hands and wear dark glasses</b> . The type of clothes you must wear are: Wide-brimmed hat: for head, neck, nose and ears Scarf: for head and neck Sunglasses with side panels: for eyes and skin around eyes Long sleeved top: for upper body/arms Long trousers: for lower body/legs Gloves: for hands, wrist and fingers Socks: for feet and ankles Closed shoes: for feet.  Do not wear very thin clothing, because it cannot protect you from strong light. Wear dark, closely woven clothing.  If you expose yourself to light by mistake, you may get a prickly or burning feeling on the skin. You must get out of the light <b>immediately</b> .  Your eyes may be very sensitive to bright lights during this week. You may get eye pain or headache when lights are switched on. If you have this problem, wear dark glasses.
<b>Days 8-14</b>	You can now begin to go outside during daylight hours. Stay in shaded areas or go out when it is cloudy. Continue to wear dark, closely woven clothing.  Start on Day 8 with 10-15 minutes outdoors. If you do not see any skin redness in the next 24 hours, you can gradually increase your time outdoors during the week.  <b>Avoid direct sunlight or strong indoor lighting. Stay in the shade.</b>
<b>Day 15 onward</b>	Your sensitivity to light is gradually getting back to normal.  You must test this carefully by exposing the back of your hand to the sun for 5 minutes. Wait 24 hours to see if there is any redness. If there is redness, you should avoid direct sunlight for another 24 hours. You can then repeat the test.  If there is no redness, you can gradually increase your exposure to sunlight day by day. Do not stay in the sunlight for more than 15 minutes the first time. Most people will be able to go back to their normal routine by Day 22.  On the first day after the skin test, you can stay in direct sunlight for 15 minutes. You can increase your exposure by another 15 minutes each day i.e. second day 30 minutes, third day 45 minutes, fourth day 60 minutes and so on. If at any time you notice a prickly or burning feeling, or see skin reddening after exposure to the sun, wait until this disappears before exposing your skin to light for this length of time again.  For 30 days following Foscan treatment, avoid eye tests that use bright lights.  For 3 months following Foscan treatment, avoid UV tanning beds. Do not sunbathe.