



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Foscan

## temoporfin

This is a summary of the European public assessment report (EPAR) for Foscan. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Foscan.

### What is Foscan?

Foscan is a solution for injection containing the active substance temoporfin (1 mg/ml).

### What is Foscan used for?

Foscan is used to relieve the symptoms of advanced head and neck squamous cell carcinoma (a type of cancer that starts in the cells lining the mouth, nose, throat or ear). It is used in patients in whom other treatments have stopped working, and who are not suitable for radiotherapy (treatment with radiation), surgery or systemic chemotherapy (medicines used to treat cancer; 'systemic' means that they are given as treatments throughout the body).

The medicine can only be obtained with a prescription.

### How is Foscan used?

Foscan must only be given in a specialist cancer centre where a team can assess the patient's treatment under the supervision of a doctor who has experience in photodynamic therapy (treatment that uses light).

Treatment with Foscan is a two-step process: the medicine is given first, and then it is activated using a laser. The medicine is given by an indwelling intravenous cannula (a thin tube permanently inserted into a vein) as a single slow injection over at least six minutes. The dose is 0.15 mg per kilogram body weight. Four days later, the entire surface of the tumour and the surrounding 0.5 cm margin is illuminated with light from a laser at a specific wavelength, using a fibre-optic cable. Each area of the



tumour should be illuminated only once during each treatment. During treatment, other areas of the body should be shielded from the light so that the activation of the medicine is limited to the tumour. If a second treatment is necessary, this should take place at least four weeks later.

## **How does Foscan work?**

The active substance in Foscan, temoporfin, is a photosensitising agent (a substance that changes when exposed to light). When Foscan is injected, temoporfin is distributed within the body, including within the tumour. When it is illuminated with laser light of a specific wavelength, temoporfin is activated and reacts with oxygen in the cells to create a highly reactive and toxic type of oxygen. This kills the cells by reacting with and destroying their components, such as their proteins and DNA. By restricting the illumination to the tumour, cell damage is limited to the tumour cells, leaving other areas of the body unaffected.

## **How has Foscan been studied?**

Foscan has been studied in four main studies involving a total of 409 patients with head or neck cancer. The first three studies looked at whether the tumour was eradicated after up to three treatments with Foscan in a total of 189 patients. The fourth study looked at the reduction of symptoms in 220 patients with advanced head or neck cancer who could not receive surgery or radiotherapy. In all studies, the response was assessed between 12 and 16 weeks after the final treatment with Foscan, but Foscan was not compared with any other treatment.

## **What benefit has Foscan shown during the studies?**

The results of the first three studies were insufficient to support the use of Foscan in the eradication of head and neck cancer tumours. However, in the study looking at improving symptoms of advanced head and neck cancer, 28 (22%) of the 128 patients assessed had a significant improvement in their most troubling symptom. Around a quarter of the patients in this study also had a reduction in tumour size.

## **What is the risk associated with Foscan?**

The most common side effects with Foscan (seen in more than 1 patient in 10) are pain in the illuminated area (such as pain in the face), headache, pain at the injection site, haemorrhage (bleeding), scarring, necrotising stomatitis (death of cells or tissue in the mouth), dysphagia (difficulty swallowing), oedema (swelling) in the illuminated area (such as swelling of the face and tongue) and constipation. For the full list of all side effects reported with Foscan, see the package leaflet.

Foscan must not be used in people who are hypersensitive (allergic) to temoporfin or any of the other ingredients. Foscan must not be used in patients with porphyria (an inability to break down porphyrins), other diseases made worse by light, allergy to porphyrins, or tumours that are spreading into a main blood vessel in or next to the area where the laser is to be shone. Foscan must also not be used in patients who have an operation planned in the next 30 days, who have an eye disease that is likely to need examination using a 'slit lamp' (an instrument used by eye specialists to look into the eye) in the next 30 days, or who are already being treated with a photosensitising agent.

Patients receiving Foscan should take care to avoid exposure to sun light or bright light for two weeks after injection to avoid skin burns. Further care must be taken for up to six months. See the package leaflet for full details.

## **Why has Foscan been approved?**

The CHMP concluded that Foscan's effects on relieving the symptoms associated with advanced head and neck cancer were of interest. Therefore, the Committee decided that Foscan's benefits are greater than its risks and recommended that it be given marketing authorisation.

## **Other information about Foscan**

The European Commission granted a marketing authorisation valid throughout the European Union for Foscan on 24 October 2001.

The full EPAR for Foscan can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Foscan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.