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EPAR summary for the public

PhotoBarr

porfimer sodium

This is a summary of the European public assessment report (EPAR) for PhotoBarr. 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 PhotoBarr.

What is PhotoBarr?

PhotoBarr is a powder that is made up into a solution for injection. It contains the active substance porfimer sodium.

What is PhotoBarr used for?

PhotoBarr is used in photodynamic therapy (treatment using light) for the ablation (destruction) of high-grade dysplasia (abnormal cells at high risk of turning into cancer) in patients with Barrett's oesophagus. This is a disease where the lining at the lower end of the oesophagus (gullet) has changed because of damage due to acid from the stomach.

Because the number of patients with Barrett's oesophagus is low, the disease is considered 'rare', and PhotoBarr was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 March 2002.

The medicine can only be obtained with a prescription.

How is PhotoBarr used?

Photodynamic therapy with PhotoBarr should only be carried out or supervised by a doctor who has experience in laser treatment using an endoscope (a thin tube used to look into the body) and who has been trained in photodynamic therapy. PhotoBarr should also only be used if experienced staff and material for assessing and treating anaphylaxis (severe allergic reaction) are immediately available.

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Treatment with PhotoBarr is a two-step process: the medicine is given first before it is activated using a laser. PhotoBarr is given by slow, careful injection into a vein at a dose of 2 mg per kilogram body weight over three to five minutes. Around two days later, the dysplasia, plus small areas of normal tissue above and below it, is illuminated with light from a laser at a specific wavelength using a fibre optic cable through an endoscope. The type of apparatus used, as well as the duration of the illumination, depends on how large the disease area is. If necessary, patients may receive a second, shorter laser treatment two to three days later. Up to two additional treatment courses (one injection and one or two laser treatments) can be given, separated by at least three months, as long as the risk of narrowing of the gullet is taken into account.

Patients who receive PhotoBarr must be given a special card that summarises the safety information on the medicine.

How does PhotoBarr work?

The active substance in PhotoBarr, porfimer sodium, is a photosensitising agent (a substance that changes when exposed to light). When PhotoBarr is injected, porfimer is absorbed into cells throughout the body. When it is illuminated with laser light of a specific wavelength, it is activated and reacts with oxygen in the cells to create a highly reactive and toxic type of oxygen called 'singlet oxygen'. This kills the cells by reacting with and destroying their components, such as their proteins and DNA. By restricting the illumination to the area of dysplasia, only cells in this area are damaged, leaving other areas of the body unaffected.

How has PhotoBarr been studied?

PhotoBarr has been studied in one main study involving 208 patients who had Barrett's oesophagus with high-grade dysplasia. The effects of photodynamic therapy with PhotoBarr, used in combination with omeprazole (an antacid medicine), were compared with those of omeprazole alone. The main measure of effectiveness was the number of patients who had no high-grade dysplasia left at least six months after the first course of treatment. Patients were followed up for at least two years.

What benefit has PhotoBarr shown during the studies?

Adding photodynamic therapy using PhotoBarr to omeprazole treatment increased the number of patients whose dysplasia was destroyed. After six months, 72% of the patients using PhotoBarr in combination with omeprazole had no high-grade dysplasia left, compared with 31% of those taking omeprazole alone. A similar difference was seen between the two groups after two years.

What is the risk associated with PhotoBarr?

The most common side effects with PhotoBarr (seen in more than 1 patient in 10) are dehydration, oesophageal stenosis (narrowing of the oesophagus), vomiting, dysphagia (difficulty swallowing), constipation, nausea (feeling sick), photosensitivity reactions (sunburn-like reactions) and pyrexia (fever). Because it causes difficulty swallowing, including pain, nausea and vomiting, patients should only take liquid food for a few days after laser treatment, and for up to four weeks in some cases. For a more complete list of the side effects reported with PhotoBarr, see the package leaflet.

PhotoBarr should not be used in people who may be hypersensitive (allergic) to porfimer sodium and other porphyrins, or to any of the other ingredients. PhotoBarr must not be used in patients with porphyria (an inability to break down porphyrins), severe problems with the liver or kidneys, varices (swollen veins) in the oesophagus or stomach, large ulcers in the oesophagus, fistulae (abnormal

passageways) between the oesophagus and either the trachea (windpipe) or the bronchi (airways in the lungs), or suspected damage to major blood vessels.

As all patients receiving PhotoBarr become more sensitive to light, they should take care to avoid exposure of their skin and eyes to bright light for at least three months after injection. See the package leaflet for full details.

Why has PhotoBarr been approved?

The CHMP decided that PhotoBarr's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of PhotoBarr?

The company that makes PhotoBarr is preparing educational materials in agreement with medicines regulatory authorities in Member States. This will ensure that all doctors and pharmacists who will prescribe or dispense the medicine are provided with information packs for healthcare workers and patients. The packs will include information on PhotoBarr and how it should be used safely.

Other information about PhotoBarr

The European Commission granted a marketing authorisation valid throughout the European Union for PhotoBarr on 25 March 2004.

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

The summary of the opinion of the Committee for Orphan Medicinal Products for PhotoBarr can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 08-2011.