EMA/31239/2016
EMEA/H/C/000305

EPAR summary for the public

Visudyne

verteporfin

This document is a summary of the European Public Assessment Report (EPAR) for Visudyne. 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 Visudyne.

What is Visudyne?

Visudyne is a medicine that contains the active substance verteporfin. It is available as a powder that is made up into a solution for infusion (drip) into a vein.

What is Visudyne used for?

Visudyne is used to treat adults with:

- the 'wet' form of age-related macular degeneration (AMD), a disease which affects the central part of the retina (called the macula) at the back of the eye. The wet form of AMD is caused by choroidal neovascularisation (abnormal growth of blood vessels under the macula), which may leak fluid and blood and cause swelling. Visudyne is used when the neovascularisation is 'predominantly classic' (when the blood vessels affected are well defined on an eye scan) and subfoveal (occurs in the area under the fovea - the central area of the macula);
- choroidal neovascularisation caused by pathologic myopia (a severe type of short-sightedness where the eyeball continues to grow, becoming longer than it should be). Visudyne is used when the neovascularisation is subfoveal

The medicine can only be obtained with a prescription.

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How is Visudyne used?

Visudyne should only be given by ophthalmologists (eye specialists) who have experience in the management of patients with AMD or pathological myopia.

Treatment with Visudyne is a two-step process. First, the patient receives Visudyne as an infusion into a vein lasting 10 minutes. The dose depends on the body surface area (calculated using the patient's height and weight). The second step, 15 minutes after the start of the infusion, is the activation of Visudyne in the eye using light generated by a laser beam. If necessary, the other eye can be treated with the laser immediately afterwards. Treatment can be repeated every three months if necessary.

How does Visudyne work?

The active substance in Visudyne, verteporfin, is a photosensitising agent (a substance that changes when exposed to light). It is used in 'photodynamic therapy', a method of treatment that uses light (generally from a laser) to activate a photosensitising agent. When Visudyne is injected into a patient, verteporfin is distributed within the body through the blood vessels, including the blood vessels at the back of the eye. When the laser light is shone into the eye, verteporfin is activated and generates toxic oxygen molecules which block blood vessels, damage and even kill cells. This helps to close up the abnormal blood vessels that cause AMD.

How has Visudyne been studied?

Visudyne has been compared with placebo (a dummy treatment) in two studies involving a total of 609 AMD patients with classic subfoveal neovascularisation, and in one study involving 120 patients with neovascularisation caused by pathologic myopia. In all three studies, the main measure of effectiveness was the number of patients who had responded to treatment after a year, measured using a standard eye test chart. A patient was classified as a responder if the number of letters that they could see increased, stayed the same, or fell by less than 15. Some of these patients went on to receive Visudyne for up to five years.

Visudyne has also been compared with placebo in 'occult' subfoveal choroidal neovascularisation (when the blood vessels affected are not well defined on the scan), in a two-year study involving 339 patients. This was followed by a confirmatory study in a further 364 patients that was carried out at the request of the CHMP.

What benefit has Visudyne shown during the studies?

Visudyne was more effective than placebo in the studies of AMD and pathologic myopia. In the two studies of wet AMD, 61% of the patients receiving Visudyne had responded to treatment after a year (246 out of 402), compared with 46% of those receiving placebo (96 out of 207). In the study of pathologic myopia, 86% of the patients receiving Visudyne had responded after a year (70 out of 81), compared with 67% of those receiving placebo (26 out of 39). The benefit of Visudyne was maintained for up to five years for both diseases.

Although the first study in occult disease showed some effectiveness, this was not confirmed in the second study. The benefit of Visudyne in occult subfoveal choroidal neovascularisation has not been established.

What is the risk associated with Visudyne?

The most common side effects with Visudyne (seen in between 1 and 10 patients in 100) are hypercholesteraemia (high blood cholesterol levels), hypersensitivity (allergic reactions), severely reduced visual acuity (very unclear vision), visual impairment (such as unclear vision, blurred fuzzy vision or flashes of light), defects in the visual field (such as small areas of reduced vision, grey or dark haloes, and black spots), dyspnoea (shortness of breath), nausea (feeling sick), photosensitivity reactions (sunburn-like reactions following exposure to light), reactions at the injection site (pain, swelling, inflammation and leakage of fluid from the veins), asthenia (weakness), infusion-related pain (mainly chest and back pain), syncope (fainting), headache and dizziness.

Visudyne must not be used in patients with porphyria (an inability to break down chemicals called porphyrins) or in patients with severe liver disease. For the full list of restrictions and side effects reported with Visudyne, see the package leaflet.

Why has Visudyne been approved?

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

Other information about Visudyne:

The European Commission granted a marketing authorisation valid throughout the European Union for Visudyne on 27 July 2000.

The full EPAR for Visudyne can be found 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 Visudyne, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.