The FOCUS ON ACCESS™ (FOA) program helps patients secure access for Visudyne® (verteporfin for injection)

Reimbursement counseling
- FOA counselors will help to determine if Visudyne® (verteporfin for injection) is covered by a patient’s insurance plan and will provide information concerning how to address prior authorizations, claim denials, and appeals
- Insurance coverage for Visudyne can be verified by FOA prior to starting treatment with Visudyne
  - If Visudyne is not covered by a patient’s insurance, FOA can provide information regarding other potential sources of access upon request

Patient assistance
- Patients without insurance coverage or whose insurance plans do not cover Visudyne, may be provided Visudyne at no cost if they meet eligibility requirements
- Enrollment forms can be printed from the Visudyne website www.visudyne.com
- FOA enrollment forms completed by both patient and physician can be mailed or faxed (patient financial information is only required if patient is seeking assistance)

FOA counselors are available via toll-free hotline
Call (866) 272-8838, Monday–Friday 9AM to 5PM EST

Please see Important Safety Information on next page and click here for full Prescribing Information.
Indications and Usage

Visudyne® (verteporfin for injection) is indicated for the treatment of predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

There is insufficient evidence to indicate Visudyne for the treatment of predominantly occult subfoveal choroidal neovascularization.

Important Safety Information

- Visudyne® (verteporfin for injection) is contraindicated for patients with porphyria or known hypersensitivity to any of its components.

- Avoid exposure of skin and eyes to direct sunlight or bright indoor light for 5 days. If extravasation occurs during infusion, the extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of a local burn which could be severe. If emergency surgery is necessary within 48 hours after treatment, as much of the internal tissue as possible should be protected from intense light.

- Patients who experience severe vision decrease (≥4 lines within 1 week) should not be retreated until their vision completely recovers to pretreatment levels and potential benefits and risks of subsequent treatment are carefully considered.

- Use of incompatible lasers that do not provide the required characteristics of light for photoactivation of Visudyne could result in incomplete treatment due to partial photoactivation or overtreatment due to overactivation, or damage to surrounding normal tissue.

- For injection of Visudyne, avoid small hand veins in favor of the largest possible arm vein, preferably the antecubital vein.

- The most frequently reported adverse events (10% to 30% incidence) were injection site reactions (including pain, edema, inflammation, extravasation, rashes, hemorrhage, and discoloration), and visual disturbances (including blurred vision, flashes of light, decreased visual acuity, and visual field defects, including scotoma).

Click here for full Prescribing Information.
Verteporfin for injection

**DESCRIPTION**
Verteporfin for injection is a light-activated drug used in photodynamic therapy. The related drug product is a yellowish dark green solution.

**Classified data**
- CAS number: 101486-11-9
- Molecular formula: C41H42N4O8
- Molecular weight: 692.72
- PEGylated phosphatidylethanolamine

**PHARMACOLOGY**
- **Mechanism of Action**
  - Verteporfin, a prodrug, is activated by photodynamic therapy (PDT).
  - Following intravenous infusion, verteporfin exhibits a bi-exponential elimination curve, with a terminal half-life of approximately 1.4 hours.
  - The extent of exposure and the maximal plasma concentration are proportionate to the dose, between 0.10 mg and 0.25 mg.
  - The pharmacokinetic parameters are not significantly affected by gender.

**Indications**
- **Presumed Ocular Histoplasmosis Syndrome**
  - Verteporfin PDT is indicated for treatment of choroidal neovascularization (CNV) secondary to presumed ocular histoplasmosis syndrome. The treatment is administered to patients with classic subfoveal CNV.

**Contraindications**
- Verteporfin for injection is contraindicated in patients with photophobia or a known hypersensitivity to any component of this preparation.

**WARNINGS**
- Photodynamic therapy with Verteporfin is associated with a long-term risk of ocular neovascularization.

**Precautions**
- **Special Populations**
  - Standard precautions should be taken during infusion of Verteporfin. Photodynamic therapy is associated with a long-term risk of ocular neovascularization.

**Drug Interactions**
- **Verteporfin and Light**
  - Verteporfin photodynamic therapy has been reported to result in the activation of light-sensitive drugs.

**Adverse Reactions**
- **Most Common**
  - Visual disturbances, photophobia, and possibly other ocular adverse events.

**Dosage and Administration**
- **Indications**
  - In patients with predominantly classic CNV lesions that do not contain occult CNV, the treatment is administered to patients with classic subfoveal CNV.

**Limitations**
- **Verteporfin and Light**
  - Verteporfin PDT is associated with a long-term risk of ocular neovascularization.

**Absorption**
- **Verteporfin and Light**
  - Verteporfin is rapidly eliminated by the liver, mainly as unchanged drug.
Calcium channel blockers, propylthiouracil or radiation therapy can enhance the effect of verteporfin. Other phototoxic drugs or agents (e.g., benzocaine, sulfonamides, phenothiazines, sulfinpyrazone) should be avoided. Phenytoin decreases the terminal plasma half-life of verteporfin. Other phototoxic oxygen species or oxygen radicals, such as dichlorodifluoromethane, p-chlorophenol, and benzalkonium chloride, can also be expected to decrease verteporfin efficacy.

Drugs that decrease clotting, vasodilatation or platelet aggregation, e.g., aspirin, dipyridamole, clopidogrel, prasugrel, ticlopidine and ticagrelor, can decrease the efficacy of Verteporfin. Light exposure, including sunlight, can decrease efficacy.

None of these factors has been evaluated to the carcinogenic potential of verteporfin. "Prostacyclin (PGI2) receptor antagonists have been shown to induce DNA damage including chromosomal exchange, sister chromatid exchange, and chromosomal aberrations in human embryo kidney (HEK293) and mouse L5178Y cells. In addition, other prostacyclin (PGI2) receptor antagonists have shown lack or decrease of teratogenicity in pregnant mice.

In pregnant rabbits, a decrease in body weight gain and food consumption was observed in normal rabbits which received verteporfin for injection intravenously. However, there were no increases of incidence of any organ anomalies or skeletal anomalies. Male rabbits of dams administrated 25 mg/kg/day during gestation showed an increased incidence of ossification in heart and long bones. In fetal rabbits, a decrease in body weight gain and food consumption was observed in normal rabbits which received verteporfin for injection intravenously. However, there were no increases of incidence of any organ anomalies or skeletal anomalies.

Verteporfin and its diacid metabolite have been found in the breast milk of mothers who received verteporfin for injection intravenously at a dose of 6 mg/m2. The milk concentration of these analytes were not evaluated. It is known that the potential for DNA damage, including mutagenesis, is present. Verteporfin has been classified as a class A non-genotoxic carcinogen and a class C genotoxic carcinogen based on in vivo and in vitro studies. The potential for genotoxicity of Verteporfin is unknown. Due to the non-monotonic nature of potential genotoxic and carcinogenic endpoints, additional studies are needed to determine if genotoxic and carcinogenic endpoints are present in the human population.

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