**INDICATIONS AND USAGE**

Initial U.S. Approval: 2000

VISUDYNE® (verteporfin for injection), for intravenous use

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

- **INDICATIONS AND USAGE**
  - VISUDYNE is indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, photodynamic therapy (PDT) or subfoveal chordoid neovascularization (CNV) due to myopic degeneration. Patient should also have documented, prior inadequate response to standard anti-VEGF therapy. 
  - The recommended light dose is 50 J/cm² of neovascular lesion administered at an intensity of 600 mW/cm².
  - The treatment spot size should be 1000 microns larger than the GLD of the lesion on the retina to allow a 500 micron border. The GLD of the lesion on the fluorescein angiogram must be corrected for the magnification of the fundus camera to obtain the true lesion size. 
  - For patients with predominantly classic CNV, blood and/or blocked fluorescence, and any serous detachments of the retinal pigment epithelium (RPE) on fluorescein angiography, therapy may be repeated. 

**DOSAGE AND ADMINISTRATION**

- A course of VISUDYNE therapy is a two-step process requiring administration of both drug and light.
- It is strongly recommended that the largest arm vein be utilized for the intravenous (IV) line. 
- VISUDYNE is a green solution. VISUDYNE may precipitate in saline solutions. Do not use normal saline or other parenteral solutions, except 5% dextrose.
- Reconstituted VISUDYNE must be protected from light and used within 4 hours. It is recommended that reconstituted VISUDYNE be stored at room temperature or refrigerated. 
- To report SUSPECTED ADVERSE REACTIONS, contact Boehringer, a division of Hoffman-La Roche Inc., or www.fda.gov/medwatch. 

**ADVERSE REACTIONS**

- **Overall common adverse reactions (≥5%)**
  - Visual disturbances
  - Injection site reactions

**FULL PRESCRIBING INFORMATION**

Revised: 02/2017

**CONTRAINDICATIONS**

- VISUDYNE is contraindicated for patients with porphyria or a known hypersensitivity to any component of the preparation.

**WARNINGS AND PRECAUTIONS**

- **Injection Site Reactions**
  - Injection site reactions may occur at any time during or following the drug administration. If injection site reactions are prolonged, discontinue therapy.
  - In case of extravasation 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 local burns, which could be severe. Cool compresses should be applied to the injection site. Cold compresses for pain relief may be administered.
  - **Exposure to Sun or Direct Light**
    - Follows steps given with VISUDYNE, care should be taken to avoid exposure of skin to direct light or sunlight. In the event of extravasation during infusion, the extravasation area must be thoroughly protected from direct light until the swelling and discoloration have faded in order to prevent the occurrence of a local burn which could be severe. If emergency procedures require needle work after treatment, it is crucial to inform the implant surgeon of the possibility of visual damage.

**ADVERSE REACTIONS**

Patients who experience systemic decreases of vision of 10 or more letters within 4 weeks after treatment should be excluded, at least until the vision has returned to baseline levels and the patient has completed all dosing cycles. 

**ADVERSE REACTIONS**

- **Clinical Laboratory Tests**
  - Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

**References**


**For more information**


**For more information**

Risk Summary

8.2 Lactation

An overdose of drug will also result in the prolongation of the period during which treatment effect was seen with increasing age. Approximately 90% of the patients treated with VISUDYNE in the clinical efficacy trials were over the age of 65. A reduced

Because of the potential for serious adverse reactions in nursing infants from VISUDYNE, a decision should be made whether to discontinue the drug’s use in such patients.

14.1 Other Special Populations

This drug is not indicated for use in patients with visual field defects.

The difference between treatment groups statistically favored VISUDYNE at the 1-year analysis but not at the 2-year analysis for visual acuity endpoints. For the primary efficacy parameter (percentage of patients who had less than 3 lines of visual acuity loss in the study eye), the difference between treatment groups was statistically significant at the 1-year analysis (p = 0.0012), but not at the 2-year analysis (p = 0.21).

8 USE IN SPECIFIC POPULATIONS

8.1 Breastfeeding

The use of VISUDYNE in clinical practice where these reactions were reported voluntarily from a population of unknown size may not reflect the information that would be obtained more precisely in a well-conducted clinical study.

The objective of the randomized extension study was to evaluate the long-term safety and efficacy of VISUDYNE in patients with classic CNV. The study population consisted of 262 patients with classic CNV who had previously received 2 or more treatments with VISUDYNE. Patients were randomized to either continued treatment at the same schedule and dosing as in the earlier studies or to placebo treatment every 4 weeks. The study included a 1-year follow-up period and was open to patients who demonstrated recurrence of CNV activity in the study eye following retreatment.

8.2 Lactation

The treatment dosing and retreatments for VISUDYNE were the same as the those described in section 14.1 Other Special Populations. The difference between treatment groups statistically favored VISUDYNE at the 1-year and 2-year analyses for visual acuity endpoints. However, the difference between treatment groups was statistically significant only for the 1-year analysis (p = 0.0012), but not at the 2-year analysis (p = 0.21).

The subgroup of patients with predominately classic CNV lesions was more likely to exhibit a treatment benefit (N=242; 86% for VISUDYNE patients compared to 67% for placebo patients). However, these benefits were not observed in the subgroup of patients with predominantly occult CNV lesions (N=163; 44% for VISUDYNE patients compared to 40% for placebo patients).

15.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The use of VISUDYNE in patients with or at risk for neovascular AMD is more likely to result in a treated area with a greater rate of visual field loss than a comparable untreated area.