


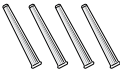







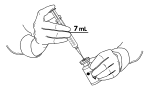

Recommended VISUDYNE® (verteporfin for injection) Preparation Guide

MATERIALS RECOMMENDED

 15-mg VISUDYNE	 Sterile Water for Injection	 D ₅ W 50 mL	 3 to 4 needles	 3 to 4 10- to 20-mL syringes	 30-mL syringe for infusion pump	 1.2-micron sterile filter	 IV catheter/infusion line
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1. PLEASE BE SURE TO HAVE A STRONG, VIABLE, OPEN VEIN BEFORE RECONSTITUTING THE VISUDYNE.

2. VISUDYNE DRUG RECONSTITUTION

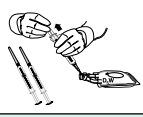
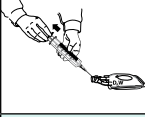
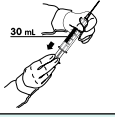


		
Withdraw Water for Injection	Inject water into VISUDYNE powder	Gently agitate to fully reconstitute VISUDYNE

- Withdraw 7 mL of sterile Water for Injection into a 10- to 20-mL syringe using a standard syringe needle
- Inject the sterile water into a 15-mg vial of VISUDYNE (verteporfin for injection) powder
- Gently agitate the vial until fully reconstituted and set aside with needle still attached
- Reconstituted VISUDYNE must be protected from light and used within 4 hours. It is recommended that reconstituted VISUDYNE be inspected visually for particulate matter and discoloration prior to administration. Reconstituted VISUDYNE is an opaque dark green solution
- Calculate the patient's body surface area (BSA) from height and weight using a standard nomogram, BSA formula, or VISUDYNE BSA Slide Rule Calculator

$$\text{Formula for BSA} = \sqrt{\frac{\text{Height (in)} \times \text{Weight (lb)}}{3131}}$$

- For appropriate volume mixture:
 - $6 \text{ mg/m}^2 \times \text{BSA} = \text{Total Drug Dose}$
 - $\text{Total Drug Dose} \div 2.0 \text{ mg/mL} = \text{Volume of Reconstituted VISUDYNE}$
 - $30 \text{ mL} - \text{Volume of Reconstituted VISUDYNE} = \text{Volume of D}_5\text{W}$

3. VISUDYNE DILUTION

				
Withdraw 5mL D ₅ W into 210- to 20-mL syringes. Set aside.	Withdraw D ₅ W: 30 mL minus VISUDYNE volume	Aspirate excess air to 30 mL	Withdraw VISUDYNE (2 mg/mL) dosage according to BSA calculation	Dilute reconstituted VISUDYNE with D ₅ W

- Withdraw 5mL D₅W into 210- to 20-mL syringes. Set aside. One syringe should be used to check patency before infusion; the other to flush the line after.
- Withdraw the calculated amount of D₅W into a 30-mL syringe using a standard syringe needle
- Pull back the plunger to aspirate excess air to the 30-mL line, leaving space to add the VISUDYNE
- Withdraw the appropriate volume of VISUDYNE into the 10- to 20-mL syringe used to reconstitute the drug
- Remove the needle from the 30-mL syringe and add the VISUDYNE through a standard syringe needle to the D₅W
- The total volume will now be 30 mL
- Prepare infusion according to standard practice, using a 1.2-micron sterile filter
- Do not use normal saline or other parenteral solutions, except 5% Dextrose for Injection, for dilution of the reconstituted VISUDYNE
- Do not mix VISUDYNE in the same solution with other drugs

INDICATION

VISUDYNE® (verteporfin for injection) therapy is a photoenhancer indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization (CNV) 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 CNV.

Please see Important Safety Information below and accompanying Full Prescribing Information [here](#).

ADDITIONAL INFORMATION

Have a product question? We have a product answer.

Product Information: If you have a general question about product information, or clinical inquiries, contact Bausch + Lomb Customer Service at 1-800-553-5340 or visit the VISUDYNE website at www.visudyne.com.

Express Delivery: When you need expedited delivery of VISUDYNE, we've made sure there are distribution resources available to you. Contact the following carrier when you need a shipment of VISUDYNE delivered quickly:

Besse Medical Phone: 1-888-767-7123
Web: www.besse.com

FOCUS ON ACCESS™ A patient support program

Upon request, FOCUS ON ACCESS™ offers the following services:

Reimbursement Support

- Investigate insurance coverage availability
- Provide information about prior-authorization, claim denials and appeals processes

Patient Assistance

- FOCUS ON ACCESS™ will assist in determining eligibility requirements for the Patient Assistance Program if patients don't have insurance or the product prescribed is not covered by their insurance plan

If you have questions about FOCUS ON ACCESS™ services, please contact us directly at (866) 272-8838. FOA counselors are available Monday through Friday, 9AM to 5PM Eastern Standard Time.

Bausch + Lomb is committed to providing high-quality resources and programs to physicians who prescribe and patients who use VISUDYNE. We are here to support your patients with any questions they may have.

IMPORTANT SAFETY INFORMATION

- VISUDYNE® (verteporfin for injection) is contraindicated for patients with porphyria or known hypersensitivity to any component of this preparation.
- Standard precautions should be taken during infusion of VISUDYNE to avoid extravasation, including but not limited to:
 - A free-flowing intravenous (IV) line should be established before starting VISUDYNE infusion and the line should be carefully monitored.
 - Due to the possibly fragility of vein walls of some elderly patients, it is strongly recommended that the largest arm vein possible, preferably the antecubital, be used for injection.
 - Small veins in the back of the hand should be avoided.
- Extravasation of VISUDYNE, especially if the affected area is exposed to light, can cause severe pain, inflammation, swelling or discoloration at the injection site. Necrosis at the injection site following extravasation has been reported. If extravasation does occur, the infusion should be stopped immediately. The extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of local burn, which could be severe. Cold compresses should be applied to the injection site. Oral medication for pain relief may be administered.
- Following injection with VISUDYNE, care should be taken to avoid exposure of skin or eyes to direct sunlight or bright indoor light for 5 days. 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 decrease of vision of 4 lines or more within 1 week after treatment should not be retreated, at least until their vision completely recovers to pretreatment levels and potential benefits and risks of subsequent treatment are carefully considered by the treating physician.
- Cases of anaphylactic reactions have been reported. Immediately discontinue VISUDYNE and initiate appropriate therapy if anaphylactic or other serious allergic reactions occur during or following therapy.
- The most frequently reported adverse events (occurring in approximately 10%-30% of patients) 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).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying Full Prescribing Information [here](#).

BAUSCH + LOMB

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Visudyne®
verteporfin for injection