CONSUMER INFORMATION
IMPORTANT: PLEASE READ

[Pr]VISUDYNE [*]
Verteporfin for Injection

This leaflet is Part III of a three-part 'Product Monograph' and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Visudyne. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
VISUDYNE is a light-activated drug used in photodynamic therapy.

VISUDYNE is used to treat the wet form of age-related macular degeneration (AMD), pathologic myopia (a severe form of nearsightedness) and presumed ocular histoplasmosis (a fungal infection of the eye). These diseases lead to vision loss because of damage to the macula, the part of the retina responsible for acute vision. Damage is caused by an ingrowth of abnormal blood vessels, called choroidal neovascularisation (CNV). These vessels leak blood and fluids (hence the term 'wet') and cause scarring. There are several patterns of leakage that can be identified in CNV, including the classic (rapidly leaking) and occult (slower leaking) patterns. VISUDYNE is used to treat the predominantly classic form of CNV.

What it does:
VISUDYNE therapy can:
- **slow vision loss,**
- **slow or stop the growth of the CNV area,**
- **reduce or stop leakage.**

VISUDYNE is injected into a vein, usually in the arm, and travels to the abnormal blood vessels in the eye. After a few minutes, the doctor shines a non-thermal laser on the affected area of the eye to activate VISUDYNE. This starts a chemical process that destroys the abnormal vessels growing in the macula.

When it should not be used:
Do not use VISUDYNE if you:
- **have porphyria, a metabolic disorder that disrupts the production of heme from precursor molecules called porphyrins, causing them to accumulate abnormally in tissues and blood. (Heme is part of hemoglobin, the protein in red blood cells that carries oxygen).**
- **are hypersensitive (allergic) to verteporfin or any of the other ingredients of VISUDYNE (see 'What the nonmedicinal ingredients are'),**
- **have severe liver impairment.**

What the medicinal ingredient is:
The active ingredient in VISUDYNE is verteporfin.

What the nonmedicinal ingredients are:
Ascorbyl palmitate, butylated hydroxytoluene, egg phosphatidylglycerol, dimyristoyl phosphatidylcholine, lactose.

What dosage form it comes in:
VISUDYNE is supplied in a glass vial with a gray stopper with an aluminium flip-off cap. It holds a powder cake which contains 15 mg verteporfin. When used, the product is made into a solution that is injected intravenously by a qualified health professional only.

WARNINGS AND PRECAUTIONS

Before using VISUDYNE, tell your doctor if you:
- **are pregnant or planning to become pregnant. Fetal malformations were seen in animal studies for one species (rat) when VISUDYNE was administered during pregnancy. Your doctor will decide with you whether the product should be used.**
- **are breastfeeding or intend to breastfeed. Visudyne appears in human breast milk. You and your doctor should discuss whether nursing should be interrupted or treatment postponed. You should not nurse for at least 96 hours after VISUDYNE administration.**
- **have liver or gall bladder problems.**
- **are using any other medications (see 'Interactions with this medication').**

Patients receiving VISUDYNE will become temporarily sensitive to light for 2 days. Therefore you must:
- **protect all parts of your skin and eyes from direct sunlight and bright indoor light. This includes tanning salons, bright halogen lighting, high power lighting used in surgical operating rooms and dental offices, and light-emitting medical devices.**
- **wear protective clothing and dark sunglasses when going outdoors. UV sunscreens are NOT effective in protecting against light sensitivity.**
- **wear a temporary wristband to remind yourself and others that you are light sensitive.**

However, you should not stay in the dark, but you should expose your skin to normal indoor lighting, because this helps break down the drug in the skin.

Accidental spills of VISUDYNE (e.g., on skin) should be wiped up immediately to avoid later photosensitivity reactions when this tissue is exposed to light. Contact with the skin and eyes should be avoided.

Following VISUDYNE therapy, you may develop a short-term disturbance in your vision. You should not attempt to drive or use machines until it goes away.

INTERACTIONS WITH THIS MEDICATION

Some drugs increase light sensitivity and could increase the potential for skin reactions or affect Visudyne activity. These include some antibiotics (tetracyclines, sulfonamides, polymyxin B) and antifungals (griseofulvin), oral diabetes drugs (sulfonylurea antihyperglycemic drugs), and drugs for mental disorders (phenothiazines).

Other drugs that may interact with VISUDYNE include drugs for heart or circulation conditions (calcium channel blockers, blood thinners or anti-clotting drugs, diuretics).

Antioxidant such as beta-carotene or drugs that scavenge free radicals (such as dimethylsulfoxide (DMSO), formate, mannitol, and alcohol) may interact with VISUDYNE.

Radiation therapy may also interact with VISUDYNE.

Make sure your doctor knows all the medications you are taking before starting VISUDYNE therapy.

PROPER USE OF THIS MEDICATION

<u>Usual adult dose:</u>
Your doctor will calculate the correct dose to give you, based on your body surface area. VISUDYNE should only be administered by a qualified health professional in an ophthalmology practice.

<u>Overdose</u>:

If your doctor tells you that you've had an overdose, you will have to protect your skin and eyes from bright light for a longer time than normal. Follow your doctor's instructions.
If you feel you have been given an overdose, consult with your doctor or healthcare practitioner administering the product immediately following the procedure, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Changes in vision (including blurring, decreased sharpness, flashes of light and gaps or 'spider webs' in vision) were among the most frequently reported side effects. If these occur, or if 'floaters' or persistent changes in visual field appear, contact your doctor (see Table). These may be signs of a serious condition.

Temporary musculoskeletal pain commonly occurs, during or after infusion, often as chest and back pain which can radiate to other areas including the pelvis, shoulder girdle or ribs.

Other common side effects include weakness, nausea, constipation, hypertension, elevated blood cholesterol or urinary glucose, dry, itchy or painful eyes, aversion to light, decrease in pain or touch sensitivity, sunburn or increased sensitivity to the sun.

Injection site reactions (e.g. pain, swelling, blisters and discolouration) may occur, and can be serious (see next section).

This is not a complete list of side effects. For any unexpected effects while taking VISUDYNE, contact your doctor or emergency care provider.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Side effect	What happens	What to do
Severe vision decrease	In clinical trials, about 1-5% of patients experienced such decreases within the first 7 days of treatment. Some patients achieved partial recovery.	Contact your doctor immediately if you have vision loss.
Changes in the visual field	Loss of vision (often sudden), appearance of light flashes, floaters.	Contact your doctor.
Hyper-sensitivity (allergic) reactions	You feel sweaty, hot or flushed, dizzy, itchy, short of breath, have a headache, hives, difficulty swallowing or feel like you are about to faint during or after receiving VISUDYNE. On rare occasions, these allergic reactions may be severe and could include seizures.	Get medical assistance immediately. Contact your doctor.
Injection site reactions	Discomfort, pain swelling, bleeding, leakage or discolouration occurs at the injection site. Light exposure can cause a painful or tissue damaging reaction.	Cover the site for as long as it is discoloured. Oral pain relievers can be taken. BE SURE to contact your doctor.

HOW TO STORE IT

Store VISUDYNE between 20 and 25°C (68-77°F).

IMPORTANT: PLEASE READ

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Before contacting* Canada Vigilance*, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp
or
http:// www.novartis.ca
or by contacting the sponsors.

Valeant Canada LP
2150 St-Elzear, Blvd., West
Laval, Quebec
Canada H7L 4A8
1-800-361-4261

Distributor:
Novartis Ophthalmics
Novartis Pharmaceuticals Canada Inc.
385 Bouchard Boulevard
Dorval, QC
H9S 1A9

1.800.363.8883

This leaflet was prepared by Valeant Canada LP

*Visudyne is a registered trademark

Last revised: January 27, 2016