

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Visudyne.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Visudyne against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Visudyne is used for

Visudyne is used to treat a condition where abnormal blood vessels grow in the back of your eye causing you to lose central vision and impairing your eyesight. The medical name for this condition is

subfoveal choroidal neovascularisation.

This condition is caused by a breakdown of the macula. The macula is part of the light sensitive layer at the back of the eye.

This medicine is a light activated drug used in photodynamic therapy (PDT). By itself, it has no effect. It works only when activated by light. It works by stopping the blood flowing to the abnormal vessels.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you are given Visudyne

When you must not be given it

You must not be given Visudyne if you have an allergy to:

- any medicine containing verteporfin
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of

the body; rash, itching or hives on the skin.

You must not be given this medicine if you have:

- porphyria
- severe liver disease

Do not breast-feed if you are given this medicine.

There is a possibility that your baby may be affected. Your doctor will advise when you can start breastfeeding again.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- gall bladder disease
- heart disease
- high blood pressure

Tell your doctor if you have been treated with Visudyne before and you experienced a decrease in vision following this previous treatment.

Visudyne has caused a severe decrease in vision shortly after treatment in a small number of patients. If this happened to you, your doctor will discuss the risk and

benefit of further treatment with Visudyne.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Visudyne.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Visudyne may interfere with each other. These include:

- some antibiotics, including tetracyclines, sulfonamides, griseofulvin and polymixin B
- phenothiazine medicines used to treat mental disorders
- some types of tablets used to treat diabetes
- some diuretic medicines (also called fluid or water tablets)
- some heart medicines called calcium channel blockers
- radiation therapy
- betacarotene included in some vitamin supplements
- medicine which decrease clotting such as aspirin
- vasodilators used to widen blood vessels resulting in smooth muscle relaxation
- alcohol
- mannitol.

These medicines may affect how well Visudyne works or may increase the chance of side effects such as making your skin or eyes more sensitive to light.

Your doctor and pharmacist have more information on medicines to be careful with or avoid when you are given this medicine.

How Visudyne is given

Your doctor will prepare and administer Visudyne for you.

Follow the directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help.

How much is given

The amount of Visudyne you need will be calculated for you and depends on your height and weight.

How it is given

Visudyne is first dissolved in water and then diluted with glucose for a total amount of 30mL infusion solution. This solution is injected slowly, over 10 minutes, into a vein.

At the end of the infusion, your doctor will put a special contact lens onto your eye and treat your eye with light from a special laser.

Follow the instructions from your doctor and keep your eye still while you are being treated with the laser.

It takes about 11/2 minutes to deliver the light dose required from the laser to activate Visudyne.

When it is given

Visudyne is given as a single dose. If necessary, it can be repeated every 3 months.

How long to continue treatment

Continue treatment with this medicine for as long as your doctor tells you.

This medicine helps to control your eye disease, but does not cure it. It is important to keep having your vision checked by your doctor even if you feel it has improved.

If you forget a treatment

If you miss a Visudyne treatment, you need to contact your doctor to arrange another appointment as soon as possible.

If you stop Visudyne treatment, your eye disease may continue to progress.

If you are given too much (overdose)

If you are given more Visudyne than you need, your doctor may ask you to protect yourself from direct sunlight, bright indoor light or surgeon's lamps for a longer period of time than the usual 48 hours.

Your doctor will advise for how long you need to do this.

While you are being given Visudyne

Things you must do

If you experience any problems during the treatment, tell your doctor.

If you experience any infusion related problems or symptoms during or following the treatment such as chest pain, , sweating, dizziness, rash, breathlessness, flushing, irregular heartbeat, or seizures, please tell your doctor or nurse immediately, as the infusion may need to be stopped and your condition may need to be treated urgently. Infusion related problems may also include sudden loss of consciousness.

If you have to go outdoors in daylight during the first 48 hours after treatment, you must protect your skin and eyes by wearing protective clothing and dark sunglasses. Avoid exposure to direct sunlight or bright indoor lights such as tanning salons, bright halogen lighting or high power lighting as used by surgeons or dentists. Also avoid prolonged exposure to light-emitting medical devices such as those which measure blood

oxygen levels. Wear the wristband which will be given to you to remind you to avoid direct sunlight for 48 hours. Sunscreens offer no protection.

When you are given Visudyne, you will become sensitive to bright light for 48 hours after the treatment.

Normal indoor lighting is safe. Do not stay in the dark because exposure to normal indoor lighting will help your body eliminate Visudyne more quickly.

If you become pregnant while being treated with this medicine, tell your doctor immediately.

Things you must not do

Do not drive or operate machinery if your vision is poor, either because of your disease or because of the treatment.

This medicine may cause temporary problems with vision in some people. If you are affected, do not drive, operate machinery or do anything else that could be dangerous until your vision is normal.

Things to be careful of

If the Visudyne solution comes into direct contact with your skin or eyes, extensively wash the affected area with water.

Visudyne contains a small amount of butylated hydroxytoluene (E321). This ingredient is an irritant to the eyes, skin and mucous membranes. If Visudyne is spilled, your doctor or his/her staff will contain the spill and wipe it up with a damp cloth.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Visudyne.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sensitivity of the skin and eyes to light or the sun
- infusion related back or chest pain which may radiate to other areas including but not limited to the pelvis, shoulders or ribs
- sunburn
- nausea, unusual tiredness or weakness
- itching
- feeling anxious
- headache
- decreased skin sensitivity
- fever, sweating, hot flushes
- pain, inflammation, swelling, blistering or leakage into the area surrounding the injection site and possibly death of skin tissue (necrosis) at the injection site. If Visudyne goes outside the vein during injection, it can cause pain, swelling and a change in skin colour in the area of the leakage. If this happens, the injection needs to be stopped and the skin treated with cold compresses and thoroughly protected from light until the skin colour returns to normal. You may need a pain killer.
- abnormal or decreased vision. Visudyne has caused a severe decrease in vision shortly after treatment in a small number of patients. Partial recovery of vision was observed in some of these patients.

The above side effects are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- eye disorder including spots, sensation of flashing light, loss of vision
- temporary blindness, or blurred vision, especially when the onset is sudden, severe and is restricted to one eye
- a change in your field of vision
- bleeding in the eye with an appearance of a spider's web in the vision
- severe allergic reactions related to Visudyne infusion including difficulty breathing or swallowing, rash, itching, hives, dizziness or redness of the skin. On rare occasions these reactions may be severe and potentially include seizures.
- fainting
- change in heart rate
- severe upper stomach pain, often with nausea and vomiting
- yellowing of the skin or eyes
- severe pain in the abdomen
- any unusual bleeding
- signs of a chest infection

The above are serious side effects which may require medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in cholesterol level, kidney or liver function, or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After you are given Visudyne

Storage

You will not need to store Visudyne. Your doctor will obtain and keep it for you.

Product description

What it looks like

Visudyne is a green powder in a clear glass vial.

Ingredients

Visudyne contains 15 mg of verteporfin as the active ingredient.

It also contains:

- lactose
- dimyristoylphosphatidylcholine
- egg phosphatidylglycerol sodium
- ascorbyl palmitate
- butylated hydroxytoluene

Sponsor

Visudyne is supplied in Australia by:

NOVARTIS Pharmaceuticals

Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

Web site: www.novartis.com.au

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