Lucentis®
Ranibizumab (rbe)
Consumer Medicine Information

What is in this leaflet
This leaflet answers some common questions about Lucentis. 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 Lucentis 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 Lucentis is used for
Lucentis is used to treat damage to the retina (light-sensitive layer at the back of the eye) caused by:

• the formation and growth of abnormal blood vessels. This is observed in diseases such as age-related macular degeneration (AMD).
• abnormal leakage of the blood vessels in the retina of diabetic patients, a disease called diabetic macular oedema (DME)
• the blockage of retinal veins which causes bleeding and swelling in the retina, a disease called retinal vein occlusion (RVO)

Lucentis inhibits both the growth and leakage of new blood vessels in the retina, abnormal processes that contribute to the progression of AMD and the development of macular oedema (swelling) due to either diabetes DME or RVO.

Lucentis contains the active substance ranibizumab, which is part of an antibody. Antibodies are proteins which specifically recognise and bind to other unique proteins in the body. Ranibizumab binds selectively to a protein called human vascular endothelial growth factor A (VEGF-A), which is present in the retina.

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 a doctor's prescription.
There is not enough information to recommend the use of this medicine for children or adolescents.

Before you are given Lucentis

When you must not be given it
You must not be given Lucentis if you have an allergy to:
• any medicine containing ranibizumab
• 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 or suspect you may have an infection in or around your eye or if you have any pain or redness in your eye.

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 are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.
Tell your doctor if you have ever had a stroke or experienced transient signs of a stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding), known as a TIA ("mini-stroke").

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

**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.

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

**How Lucentis is given**

Lucentis is given by your ophthalmologist as an injection into your eye under a local anaesthetic. Your doctor will ask you to use antimicrobial eye drops 4 times a day for 3 days before and after each injection. This is to prevent any possible eye infection.

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 usual dose is 0.05mL or 0.03mL (equivalent to 0.5mg or 0.3mg). The interval between two doses should not be shorter than one month.

If you are treated for wet age-related macular degeneration, the injection is given once a month. Your doctor will monitor your vision monthly. If your vision remains the same, your doctor may decide to stop the treatment with Lucentis. Your doctor will continue to monitor your vision monthly and decide if treatment with Lucentis should be resumed or not.

If you are treated for visual impairment due to macular oedema in RVO, the injection is given once a month for six months. Thereafter, your doctor will monitor your vision monthly and will decide if treatment with Lucentis should be resumed or not.

**If you are given too much (overdose)**

If you are given more Lucentis than you need, your doctor will check the pressure in your eye and may need to treat it if it is increased.

**While you are being given Lucentis**

**Things you must do**

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

Tell your doctor immediately if you develop signs of inflammation and/or infection of the eye such as redness of the eye, eye pain, light sensitivity and/or vision changes, seeing flashes of light with floaters (seeing cobwebs), progressing to a loss of sight or blurred vision.

A serious eye infection or eye disorder can sometimes develop after an injection into the eye.

If you are treated for visual impairment due to macular oedema in diabetes or in RVO tell your doctor if you think that the effect of the treatment is being lost.

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.
Side effects

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

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:

- eye irritation, clouding of the lens, a feeling of having something in the eye, dry eye, abnormal sensation in the eye
- eye discomfort, pain or irritation at the site of the injection, increased tear production, redness or itching of the eye, small particles or spots in your vision (floaters)
- sore throat, headache, joint pain, flu-like symptoms, fatigue, general feeling of being unwell, anxiety, cough, nausea, allergic reactions (rash, itching, redness of the skin).

The above list includes side effects of your medicine which are usually mild and short-lived.

Tell your doctor immediately if you experience any of the following:

- signs of inflammation and/or infection of the eye such as redness of the eye, eye pain, sensitivity to light and/or vision changes
- seeing flashes of light with floaters (seeing cobwebs), progressing to blurred vision or loss of sight.

Go to your nearest emergency room immediately if you experience signs of a stroke, such as weakness or paralysis of limbs or face, difficulty speaking or understanding.

If you experience any of these signs, immediate medical care is needed. The above are serious side effects which might need immediate 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 (e.g. an increase in the pressure inside your eye) can only be found when your doctor does tests to check your progress.

After you are given Lucentis

Storage

It is unlikely you will have to store Lucentis at home.

If you do have to store it:

- Keep it in a refrigerator (2°C to 8°C). Do not freeze it.
- Keep the vial in the outer carton in order to protect it from light.
- Do not store Lucentis or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep the medicine where children cannot reach it.

Each Lucentis vial and associated needles and syringe are to be used for one injection only and then discarded.

Product description

What it looks like

Lucentis is a clear, colourless to pale yellow solution in a clear, colourless glass vial. Lucentis is supplied as packs containing one glass vial containing 0.23mL of solution, one filter needle for withdrawal of the vial contents, one injection needle and one syringe for intravitreal injection.

Ingredients

Lucentis contains 2.3mg ranibizumab as the active ingredient.

It also contains:

- trehalose dihydrate
- histidine hydrochloride monohydrate
- histidine
- polysorbate 20
- water for injections.
**Sponsor**

Lucentis is supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone 1-800-671-203
Web site: www.novartis.com.au

**Date of preparation**

This leaflet was prepared in October 2011.

AUST R 148325 (2.3mg/0.23mL)

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