Lucentis®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I receiving Lucentis?

Lucentis contains the active ingredient ranibizumab (rbe). It is used to treat adults in 1) Wet age related macular degeneration (wet AMD), 2) Diabetic macular oedema (DME), 3) Oedema due to retinal vein occlusion (RVO) where fluid accumulates into the back of the eye, 4) Proliferative diabetic retinopathy (PDR), 5) CNV secondary to pathologic myopia (PM), 6) CNV due to other causes and 7) in babies born prematurely Retinopathy of Prematurity (ROP).

For more information, see Section 1. Why am I receiving Lucentis? in the full CMI.

2. What should I know before I am given Lucentis?

Do not use if you have ever had an allergic reaction to ranibizumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I am given Lucentis? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lucentis and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Lucentis?

- Lucentis is given by an ophthalmologist (eye doctor) as an injection into the eye under a local anaesthetic.
- In adult patients, the usual dose is 0.05mL. In pre-term infants, the usual dose is 0.02 mL.. Alternatively, a dose of 0.01 mL can be given in pre-term infants.

More instructions can be found in Section 4. How will I be given Lucentis? in the full CMI.

5. What should I know while I am given Lucentis?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Lucentis. • Tell your doctor if you experience signs of inflammation or infection or you become pregnant.
Driving or using machines	• Do not drive or operate machinery if your vision is poor, either because of your disease or because of the treatment.
Drinking alcohol	• There are no known interactions between Lucentis and alcohol.
Looking after your medicine	• Your ophthalmologist (eye doctor) will treat you with Lucentis. There is no need to store this medicine at home.

For more information, see Section 5. What should I know when given Lucentis? in the full CMI.

6. Are there any side effects?

Common side effects: eye discomfort, feeling of having something in the eye or the eye not feeling normal, dry eye, spots in front of the eye (floaters), teary, pain/ irritation at injection site, and allergic reactions (rash, itching, redness of the skin).

Serious side effects: bloodshot eye, bleeding in the eye, inflammation or infection of the eyelids, blurred vision or possible temporary blindness, discharge from the eye, itching redness of the eye, small marks on the eye surface, swelling or irritated eye lid, pus on the eye, urinary tract infection (burning, stinging or pain when passing urine).
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ Use of this medicinal product in paediatric ROP patients is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor or directly at www.tga.gov.au/reporting-problems.

Lucentis®

Active ingredient(s): *Ranibizumab (rbe)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lucentis. **You should also speak to your ophthalmologist, paediatric ophthalmologist (eye doctor) or pharmacist if you would like further information or if you have any concerns or questions about using Lucentis.**

Where to find information in this leaflet:

1. Why am I receiving Lucentis?
2. What should I know before I am given Lucentis?
3. What if I am taking other medicines?
4. How will I be given Lucentis?
5. What should I know while I am given Lucentis?
6. Are there any side effects?
7. Product details

1. Why am I receiving Lucentis?

Lucentis contains the active ingredient ranibizumab (rbe). Lucentis belongs to a group of medicines called antineovascularisation agents. Lucentis specifically recognises and binds to a protein called human vascular endothelial growth factor A (VEGF-A) present in the eye. In excess, VEGF-A causes abnormal blood vessel growth in the eye. Lucentis can block its actions and prevent this abnormal growth.

Lucentis is used to treat a number of eye conditions including:

In adults, damage to the retina (light-sensitive layer at the back of the eye) caused by growth of leaky, abnormal blood vessels (choroidal neovascularization, CNV) in diseases that may cause decreased vision such as:

- Wet age related macular degeneration (wet AMD)

- CNV secondary to pathologic myopia (PM)

- CNV due to other causes

- Diabetic macular edema (DME), or oedema due to retinal vein occlusion (RVO) where fluid accumulates into the back of the eye.

In babies born prematurely, Lucentis is used to treat Retinopathy of Prematurity (ROP), a disease causing vision impairment due to damage to the back of the eye (the retina) caused by abnormal growth of blood vessels.

2. What should I know before I am given Lucentis?

Warnings

Do not use Lucentis if:

- you are allergic to ranibizumab (rbe), or any of the ingredients listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- 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.
- Always check the ingredients to make sure you can use this medicine.

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 or your baby should be given this medicine, talk to your doctor.

Check with your doctor if you:

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is recommended that you use effective contraception during Lucentis treatment and for at least three months after the last injection of Lucentis.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Lucentis is not recommended during breastfeeding as it is not known whether Lucentis passes into breast milk.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lucentis.

4. How will I be given Lucentis?

How much to use

Lucentis is given by your ophthalmologist or paediatric ophthalmologist (eye doctor) as an injection into your eye under a local anaesthetic.

How Lucentis is given

Lucentis is given as a single injection into your eye.

Before the injection, you will be given an eye drop to numb the eye as well as an eye drop that can kill germs on the eye and on the skin around the eye.

After the Lucentis injection, your doctor may perform some additional tests to make sure there are no complications. Eye injections like those with Lucentis can increase eye pressure. This is something you would not notice.

How much is given

In adults, the usual dose is 0.05 mL (equivalent to 0.5mg). The time between two doses injected into the same eye should not be shorter than one month.

The treatment is started with one injection of Lucentis per month. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor will decide whether and when you need to receive the next injection of Lucentis.

In preterm infants, the usual dose is 0.02 mL (equivalent to 0.2 mg). Alternatively, a dose of 0.01 mL can be given (equivalent to 0.1mg). The time between two doses injected into the same eye should not be shorter than one month.

The treatment is started with one injection of Lucentis in each eye (some babies may only need treatment in one eye). Depending on how your baby responds to the treatment, your doctor will decide whether and when further treatment is needed.

If you forget to use Lucentis

Your eye doctor will give you Lucentis so it is not likely that you will forget to use this medicine.

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

If you stop Lucentis treatment, your eye disease may get worse.

If you are given too much Lucentis

This is unlikely as your doctor will be giving you too much Lucentis.

If you are unwell after receiving Lucentis contact your doctor.

5. What should I know while I am given Lucentis?

Things you should do

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

Call your doctor straight away if you:

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.

Remind any doctor, dentist or pharmacist you visit that you were given Lucentis.

Things you should not do

Driving or using machines

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site reactions such as: • eye irritation, clouding of the lens, a feeling of having something in the	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
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) **Other reactions such as:** • 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).	

Serious side effects

Serious side effects	What to do
Eye infection symptoms such as: • bloodshot eye, bleeding in the eye, inflammation or infection of the eyelid margins, visual	**Call your doctor if you notice any of these side effects.**

Serious side effects	What to do
disturbance, blurred or decreased sharpness of vision, blindness (temporary or otherwise) • discharge of the eye with itching, redness and swelling (conjunctivitis) • small marks on the surface of the eye, swelling of a section of the eye (cornea, uvea), swelling or irritation of the eyelid, eyelid pain, sac of pus on the eye. **Urinary tract infection:** • symptoms of a urinary tract infection, including burning, stinging, pain or increased urgency to pass water.	
Worsening of eye inflammation or infection such as: • redness of the eye, eye pain, sensitivity to light or vision changes • seeing flashes of light with floaters (seeing	**Call your doctor straight away if you notice any of these side effects.**

Serious side effects	What to do
spots or cobwebs), progressing to blurred vision or loss of sight.	
Nervous system disorders: • 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.	**Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Lucentis contains

Active ingredient **(main ingredient)**	Ranibizumab (rbe)
Other ingredients **(inactive ingredients)**	trehalose dihydrate histidine hydrochloride monohydrate histidine polysorbate 20 water for injections.
Potential allergens	May contain traces of milk and residue of tetracycline (antibiotic).

Do not use this medicine if you are allergic to any of these ingredients.

- trehalose dihydrate
- histidine hydrochloride monohydrate

- histidine
- polysorbate 20
- water for injections.

What Lucentis looks like

Vial*

Lucentis is a solution for injection supplied in a clear, colourless glass vial. The vial contains 0.23 mL of a sterile, clear, colourless to pale brownish yellow aqueous solution.

Pre-filled syringe

Lucentis is a solution for injection supplied in a pre-filled syringe. The pre-filled syringe contains 0.165 mL of a sterile, clear, colourless to pale brownish yellow aqueous solution.

*Not all presentations may be marketed.

Vial: AUST R 148325 (2.3mg/0.23mL)

Pre-filled syringe: AUST R 212387 (1.65mg/0.165mL)

Who distributes Lucentis

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Web site: www.novartis.com.au

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