Your guide to therapy with Lucentis® (Ranibizumab)

Important Safety Information

This booklet was created to help you better understand Lucentis® when used for the treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM) also known as myopic CNV, and other rare diseases.

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WHAT IS LUCENTIS®?

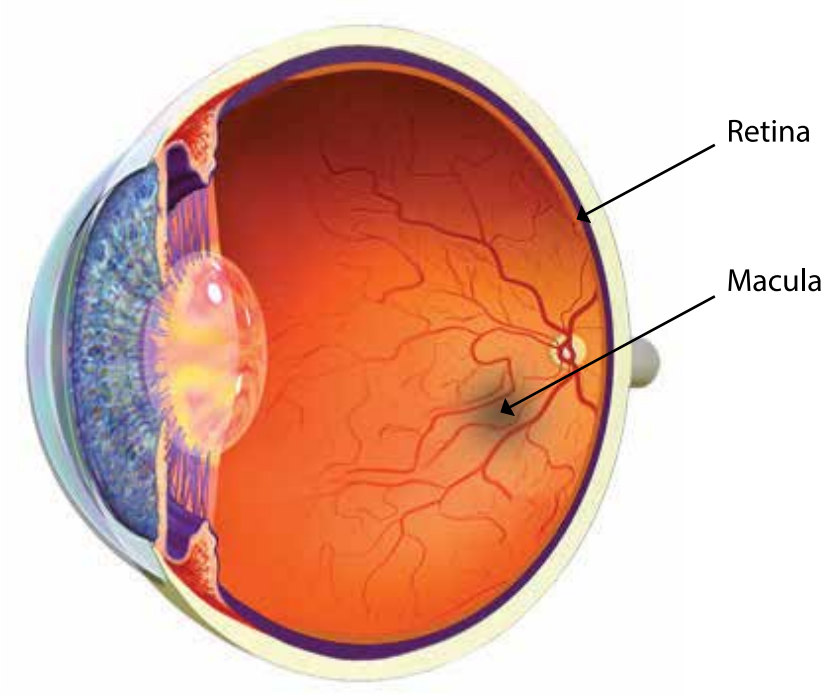
- In myopic CNV, abnormal blood vessels grow in the eye, which can leak and cause vision loss.[1]
- Lucentis® specifically recognizes and blocks the action of new blood vessel growth in the eye, and so in turn, it can help stop leakage and vision loss.[2]

1. Miller DG, Singerman LJ. *Optom Vis Sci*. 2006;83(5):316-325. **2.** Ferrara N, *et al. Retina*. 2006;26(8):859-70.

WHY HAVE I BEEN PRESCRIBED LUCENTIS®?

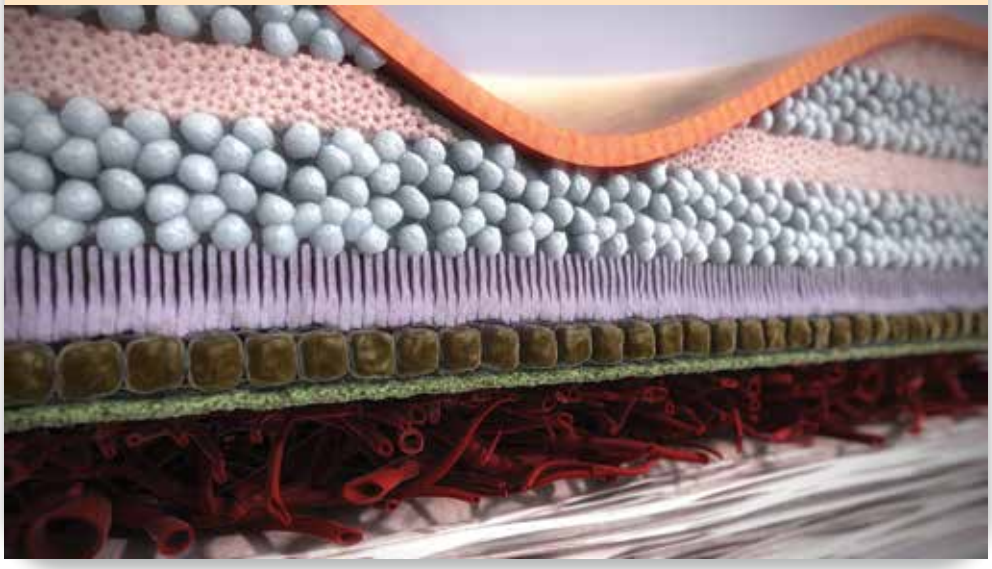
Myopic CNV

- Myopic CNV is a condition that affects the macula,[1] a part of the retina at the back of the eye.[2]
- The macula is the area that lets you see sharply in the center of your vision.[2]
- CNV is the growth of new, weak blood vessels under the macula, which can leak fluid and blood into the retina, affecting your central vision[1]
- CNV is observed in age-related macular degeneration (AMD); it may also be associated with other diseases. These include CNV due to pathologic myopia (PM), angioid streaks or central serous chorioretinopathy (CSC), and inflammatory CNV[1]

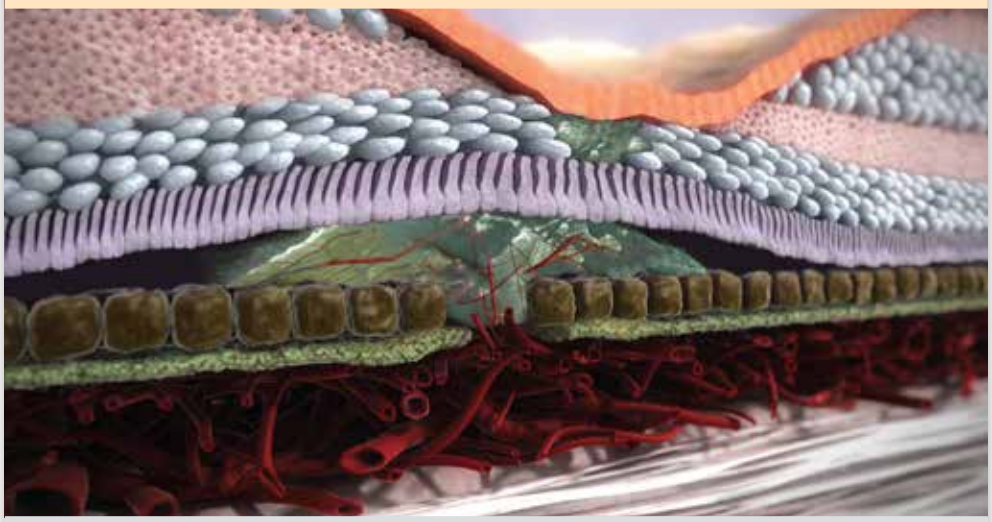


1. Miller DG, Singerman LJ. *Optom Vis Sci*. 2006;83(5):316-325; 2. Jager RD, *et al. N Engl J Med*. 2008;358(24):2606-2617.
Image: Blausen.com staff. "Blausen gallery 2014". *Wikiversity Journal of Medicine*. DOI:10.15347/wjm/2014.010. ISSN 20018762. (Own work) [CC-BY-3.0 (http://creativecommons.org/licenses/by/3.0)], via Wikimedia Commons. Available: http://commons.wikimedia.org/wiki/File:Blausen_0312_DiabeticRetinopathy.png [accessed October 2016].

Healthy retina



Retina affected by myopic CNV



New weak blood vessels grow and leak, damaging the macula.

HOW ARE RETINAL DISEASES DIAGNOSED?

- There is a range of different techniques used to examine the eye. These can be divided into two broad categories, depending on what they examine:[1]
  - > Eye function: These include techniques assessing vision (e.g., vision charts).
  - > Eye structure: These techniques examine the tissues of the eye for damage or disease.
- As well as the standard tests (vision charts, examination of the eye with a hand-held device, etc...),[1, 2] additional techniques are employed to examine eye blood vessels and tissues.[2]
- **Fluorescein angiography (OCT)** is a technique used to visualize the blood vessels at the back of the eye:[1, 3]
  - > First, the doctor will dilate your pupils with some eye drops.
  - > Next, a yellow dye will be injected into your arm. (This makes the blood vessels in your eyes glow brightly when a certain type of light is shone on them.)
  - > A series of photographs is taken.
- **Optical coherence tomography (OCT)** is a commonly used technique that produces cross-sectional images of the back of the eye:[2–4]
  - > This is a non-invasive technique[4] that just requires you to keep your head still and look into a machine while detailed images of your retina are taken without the need to touch your eye.

1. Lueck CJ, *et al. J Neurol Neurosurg Psychiatry.* 2004;75(Suppl 4):iv2-iv11. **2.** American Academy of Ophthalmology. Available: www.aao.org/Assets/dba38b76-3095-4360-8cb6-00adab3aad68/635919125497230000/diabetic-retinopathy-ppp-pdf [accessed October 2016]. **3.** Arias L, Mones J. AMD Book: Fluorescein angiography. Available: http://www.amdbook.org/content/fluorescein-angiography-0 [accessed October 2016]. **4.** Huang D, *et al. Science.* 1991;254(5035):1178-81.

HOW IS LUCENTIS® TREATMENT GIVEN?

- Lucentis® is given by your ophthalmologist (eye doctor) as an injection into the eye.
- It is normal to worry about such injections, but patients have reported that most often the injection is virtually painless and sounds worse than it is:[1]
  - > The majority of patients reported that any apprehensions about injections dissipated after the first injection.[1]

What will happen at my appointment?

- On the day of your treatment, care will be taken to make sure you are relaxed and comfortable.
- Before receiving Lucentis®, you should inform your doctor if you have had a stroke or experienced transient signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding), so that it can be decided whether this is the most appropriate treatment for you.
- Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription.
- A doctor or nurse will:
  - > Cover your face and the area around the eye with a special drape
  - > Clean your eye and the skin around it
  - > Hold your eye open so you don't blink
  - > Numb your eye with an anesthetic to prevent pain
- The doctor will then give the injection into the white part of your eye. You may feel a little pressure with the injection.
- It is important to tell your doctor if you:
  - > Have an eye infection
  - > Have any pain or redness in your eye
  - > Think you may be allergic to Lucentis® or Betadine®† (Iodine)

1. Thetford C, *et al. Br J Vis Impair.* 2013;31(2):89-101. †Betadine is a registered trademark of Mundipharma AG.

WHAT WILL HAPPEN AFTER I RECEIVE MY LUCENTIS® INJECTION?

- Your doctor will perform eye tests, such as measuring the pressure in your eye, to make sure the treatment went well.
- The white area of the eye, where the injection is given, will likely be red:
  - > This redness is normal and it will go away in a few days.
  - > Contact your doctor if it does not go away or gets worse.
- You may see a few spots or 'floaters' in your vision:
  - > These spots are normal and should go away in a few days.
  - > Contact your doctor if they do not go away or get worse.
- Your pupils will be dilated for the injection, and this can make it difficult for you to see for a few hours after the treatment:
  - > You should not drive until your vision has returned to normal.
- It is important to monitor any changes in the condition of your eye and your overall wellbeing in the week following your injection:
- Rarely can injections in the eye cause infection.
- Contact your doctor as soon as possible if you have any of the following signs and symptoms in your eye:
  - > Pain
  - > Light sensitivity/tearing
  - > Swollen lids or other swelling
  - > Increasing redness
  - > Blurred, distorted or sudden loss of vision
  - > Light flashes
  - > Seeing flies, black spots or colored halos
  - > Drying of the surface of your eye
- If you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

HOW LONG WILL I NEED TO CONTINUE LUCENTIS® TREATMENT?

- Every patient is different. It is likely that you will need additional Lucentis® injections, but this will depend on how you respond to treatment and how your vision changes.
- Talk to your doctor about your results and your feelings about your treatment.
- It is important to keep attending your eye doctor appointments:
  - > The best way to protect your independent lifestyle and your vision is to visit your doctor on a regular basis.
  - > Make sure you discuss your treatment options with your doctor.
- If you are considering stopping treatment with Lucentis®, ask your doctor for advice first.
- For any further questions on the use of this product, please ask your doctor.
- Follow all your doctor's instructions carefully. They may differ from the general information in this leaflet.

Your doctor will decide how often they wish to see you to monitor your condition and determine if you need additional injections.

Always go to every appointment that your doctor arranges for you.

If you miss an appointment for Lucentis® treatment, contact your doctor as soon as possible.

WHAT CAN I DO TO HELP IMPROVE MY VISUAL IMPAIRMENT?

- **Monitor your own vision regularly:**
  - > **At home, take note of any changes in your vision.**
  - > **Be proactive and tell your doctor or nurse if you notice any changes.**
- **Dealing with changes in your vision can be difficult. It is OK to ask for support:**
  - > **Talk with family and friends about your vision, and let them know if you are having trouble reading, getting around, taking medication or doing housework.**
  - > **If you do not have family or friends who can help, ask at your doctor's office about support services.**

Keep this booklet; you may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

If you experience any signs or symptoms that you consider to be associated with the use of Lucentis®, but are not listed in this booklet, please tell your doctor.

Please refer to SPC/PIL for more information.

LUCENTIS® **Note:** Before prescribing, consult full prescribing information. **Presentation: Vial**: Ranibizumab. Each vial contains 2.3 mg of ranibizumab in 0.23 mL solution. **Indications:** ♦Treatment of neovascular (wet) age-related macular degeneration (AMD). ♦Treatment of visual impairment due to diabetic macular edema (DME). ♦Treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO). ♦Treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM). **Dosage:** ♦The recommended dose is 0.5 mg (0.05 mL) given as a single intravitreal injection. The interval between two doses should not be shorter than 1 month. **AMD, DME RVO:** Patients should be monitored monthly for visual acuity. ♦Treatment is given monthly and continued until maximum visual acuity is achieved, confirmed by stable visual acuity for three consecutive monthly assessments performed while on Lucentis® treatment. Treatment is resumed with monthly injections when monitoring indicates a loss of visual acuity due to wet AMD, DME or macular edema secondary to RVO and continued until stable visual acuity is reached again for three consecutive monthly assessments. ♦Lucentis and laser photocoagulation in DME or in branch RVO: Lucentis has been used concomitantly with laser photocoagulation in clinical studies. When given on the same day, Lucentis should be administered at least 30 minutes after laser photocoagulation. Lucentis can be administered in patients who have received previous laser photocoagulation. **CNV secondary to PM:** Treatment is initiated with a single injection, further treatment is recommended if monitoring reveals signs of disease activity. ♦The frequency of monitoring should be determined by the treating physician. ♦Lucentis must be administered by a qualified ophthalmologist using aseptic techniques. Broad-spectrum topical microbicide and anaesthetic should be administered prior to the injection. ♦Not recommended in children and adolescents. **Contraindications:** Hypersensitivity to ranibizumab or to any of the excipients, patients with active or suspected ocular or periocular infections, patients with active intraocular inflammation. **Warnings/Precautions:** ♦Intravitreous injections have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Therefore proper aseptic injection techniques must be used. Patients should be monitored during the week following the injection to permit early treatment if an infection occurs. ♦Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of injection of Lucentis. Sustained IOP increases have also been reported. Intraocular pressure and the perfusion of the optic nerve head must be monitored and managed appropriately. ♦There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. A numerically higher stroke rate was observed in patients treated with ranibizumab 0.5 mg compared to ranibizumab 0.3 mg or control, however, the differences were not statistically significant. Patients with known risk factors for stroke, including history of prior stroke or transient ischemic attack should be carefully evaluated by their physicians as to whether Lucentis treatment is appropriate and the benefit outweighs the potential risk. ♦Available data do not suggest an increased risk of systemic adverse events with bilateral treatment. ♦As with all therapeutic proteins, there is a potential for immunogenicity with Lucentis. ♦Lucentis has not been studied in patients with active systemic infections or in patients with concurrent eye conditions such as retinal detachment or macular hole. ♦There is limited experience with treatment of patients with prior episodes of RVO and of patients with ischemic branch RVO (BRVO) and central RVO (CRVO). In patients with RVO presenting with clinical signs of irreversible ischemic visual function loss, treatment is not recommended. Should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus. For women who wish to become pregnant and have been treated with ranibizumab, it is recommended to wait at least 3 months after the last dose of ranibizumab before conceiving a child; use of effective contraception recommended for women of child-bearing potential; breast-feeding not recommended. ♦Following treatment patients may develop transient visual disturbances that may interfere with their ability to drive or use machines. Patients should not drive or use machines as long as these symptoms persist. **Interactions:** No formal interaction studies have been performed. **Adverse reactions: ♦Very common adverse reactions are:** intraocular inflammation, vitritis, vitreous detachment, retinal hemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival hemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperemia, eye pruritus, intraocular pressure increased, nasopharyngitis, headache, arthralgia. **♦Common adverse reactions are:** retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous hemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract, cataract subcapsular, posterior capsule opacification, punctuate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site hemorrhage, eye hemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid edema, eyelid pain, conjunctival hyperemia, stroke, influenza, urinary tract infection*, anemia, anxiety, cough, nausea, allergic reactions (rash, pruritus, urticaria, erythema). **♦Uncommon adverse reactions are:** blindness, endophthalmitis, hypopyon, hyphema, keratopathy, iris adhesions, corneal deposits, corneal edema, corneal striae, injection site pain, injection site irritation, abnormal sensation in eye, eyelid irritation. **♦Serious adverse events** related to intravitreal injections included endophthalmitis, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract.
**observed only in the DME population*
Packs and prices: Country specific.
Legal classification: Country specific.

NOVARTIS

You can report any problem or adverse events through:
Novartis Consulting AG.
Saudi Arabia: P.O. Box: 16032, Riyadh
11464, Tel.: +966 11 465 8882
DS&E
Phone: +99611 265 8100
Fax: +966 11 265 8107
E-mail: adverse.events@novartis.com
Saudi Food and Drug Authority National Pharmacovigilance Center
You can report any problem through
Toll free phone: 8002490000
Fax: +966-11-205-7662
E-mail: npc.drug@sfda.gov.sa
Or online: https://ade.sfda.gov.sa

يمكنك الابلاغ عن أي أعراض جانبية أو شكاوى من خلال:
الهيئة العامة للغذاء والدواء المركز الوطني للتيقظ الدوائي
الرقم المجاني: ٨٠٠٢٤٩٠٠٠٠
الفاكس: ٩٦٦١١٢٠٥٧٦٦٢+
الايميل: npc.drug@sfda.gov.sa
أو عن طريق الانترنت: https://ade.sfda.gov.sa/
أو شركة نوفارتس
الهاتف: ٩٦٦١١٢٦٥٨١٠٠+
الفاكس: ٩٦٦١١٢٦٥٨١٠٧+
الايميل: adverse.events@novartis.com

Lucentis EU RMP V16/ Feb 2017
LUC-RMP-EN-PT-mCNV-V16-Feb 17/SA