

Your guide to therapy with Lucentis® (ranibizumab) for visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia



Your doctor has prescribed you Lucentis®

This booklet has been created to help you better understand Lucentis®, a treatment for visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia

SECTION 1 – ABOUT LUCENTIS®

WHAT IS LUCENTIS®?

- Lucentis® belongs to a group of treatments known as anti-vascular endothelial growth factor (VEGF) therapies
- Lucentis® prevents VEGF-A (a substance that causes abnormal blood vessel growth) from causing further damage to the eye and can even repair some of the damage that has occurred

HOW IS LUCENTIS® TREATMENT GIVEN?

- Lucentis® is an injection in the eye
 - It is normal to worry about such injections,
 but most often the injection is painless

SECTION 1 – ABOUT LUCENTIS®

WHAT WILL HAPPEN AT MY APPOINTMENT?

- To help prevent any infection, your doctor may ask you to use antibiotic eye drops for a few days before the injection
- 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
- 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 and may use a device to help
 - 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 any pain or redness or discharge in your eye
 - Think you may be allergic to Lucentis® or to Betadine® (iodine)

WHAT HAPPENS AFTER I RECEIVE MY LUCENTIS® INJECTION?

- Your doctor will do eye tests, including a measure of the pressure in your eye, to make sure the treatment went well and check for any complications associated with the injection process
- You may need to use eye drops for a few days to minimize chance of infection
- 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 if they get worse
- Your pupils will be dilated for the injection, which 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

SECTION 1 – ABOUT LUCENTIS®

WHAT HAPPENS AFTER I RECEIVE MY LUCENTIS® INJECTION? (cont'd)

- It is important to monitor any changes in the condition of your eye and body in the week following your injection
- Rarely, injections in the eye can 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

HOW LONG WILL I NEED TO CONTINUE TREATMENT WITH LUCENTIS®?

- Every patient is different. You may need additional Lucentis® injections depending on how you respond to treatment
- Talk with your doctor about your results and your feelings about your treatment
- If your vision is not maintained or does not get better immediately, 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
 - Be sure to discuss options with your doctor

Always go to every appointment that your doctor arranges for you

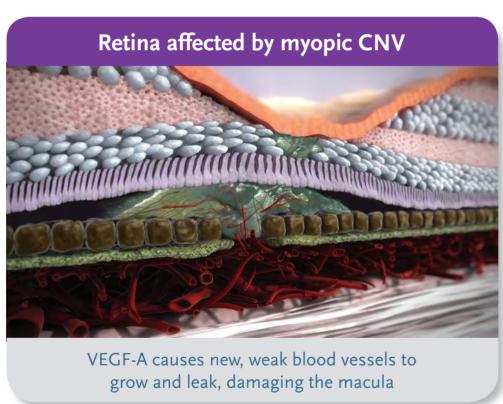
Regular monitoring is required to assess your need for treatment

WHAT IS MYOPIC CNV AND HOW DOES IT AFFECT MY VISION?

- Myopia (also known as near- or short-sightedness) is a common condition where light entering the eye is focussed in front of the retina instead of directly on it, causing distant objects to appear blurry¹
- Myopia can be classified into two groups based on its severity:
 - Low-to-modest degree of myopia (simple myopia)
 - High myopia
- Eyes with high myopia become elongated compared with normal eyes. 1-3 Many of them have signs of structural damage where tissue in the eye has deteriorated this is called pathologic myopia. 2-3
 - Invasive blood vessels growing in the layers of tissue of the retina, a process called CNV²
- Myopic CNV is a common cause of vision loss in patients with pathologic myopia and is a serious threat to vision if left untreated^{2,3}

PATHOLOGIC MYOPIA





SECTION 2 – VISUAL IMPAIRMENT DUE TO CNV SECONDARY TO

- One of the contributing factors for myopic CNV is a substance called VEGF-A^{1,2}
- VEGF-A can cause leakage and thickening in the layers of your retina that damage your vision²
- It may be that visual impairment due to myopic CNV has already started to affect your ability to do everyday things such as reading, shopping and driving
- You may need to see your doctor regularly for tests after being treated to have your progress and need for any further treatment assessed

HOW IS CNV SECONDARY TO PATHOLOGIC MYOPIA DIAGNOSED?

- A technique called fluorescein angiography, which visualizes the blood vessels at the back of the eye, is commonly used for the diagnosis of CNV secondary to pathologic myopia
- For this test, the doctor will dilate your pupils with some eye drops
- A yellow dye will then be injected into your arm and a series of photographs will be taken

WHAT CAN I EXPECT FOLLOWING TREATMENT WITH LUCENTIS®?

- For almost all patients, vision at least stays the same with Lucentis®, and improves for many patients
- Following treatment, some patients notice a difference in their vision in as early as 1 week
 - Youmay not notice an improvement right away, but it is important that you continue with regular check-ups and any scheduled treatments because you may notice improvement with continued treatment
- With Lucentis®, you may find that you are able to do everyday activities that you have found difficult since being diagnosed with visual impairment due to CNV secondary to pathologic myopia, such as reading, shopping and driving

SECTION 2 – VISUAL IMPAIRMENT DUE TO CNV SECONDARY TO PATHOLOGIC MYOPIA (cont'd)

WHAT CAN I DO TO HELP MY VISION LOSS?

- Monitor your own vision regularly
 - At home, take note of any changes in your vision
 - > Inform your doctor or nurse if you notice any changes
 - > Treatment will provide an opportunity to reduce further vision loss or improve your vision
- 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

Suspected adverse reactions and medication errors associated with the use of Lucentis (ranibizumab) should be reported to: Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/form-details

Alternatively at: Novartis Pharma Services Inc. Representative Office Malta by phone on 22983217 or 21222872