

**Your guide to therapy with LUCENTIS® (ranibizumab) for
proliferative diabetic retinopathy and, or, visual impairment due to
diabetic macular edema**

[Introduction]

Welcome to your guide to therapy with LUCENTIS®.

This guide has been created to help you better understand LUCENTIS® when used for the treatment of proliferative diabetic retinopathy, or PDR, and, or, visual impairment due to diabetic macular edema, or DME.

First, you'll learn about LUCENTIS®. Next you will learn how PDR and DME develop and how they are diagnosed. In the next sections we will talk about how LUCENTIS® treatment is given and what will happen at your appointment. Lastly, we will talk about what happens after you have received LUCENTIS® and what you can do to help prevent vision loss, in addition to receiving LUCENTIS® treatment.

[Section 1 – what is LUCENTIS®?]

To start off, what is LUCENTIS®?

In PDR and DME, damage to the retina, the light-sensitive layer at the back of the eye, results from the growth of new, abnormal, leaky blood vessels. In DME, vision loss is predominantly caused by macular edema, which is swelling of the center of the retina. LUCENTIS® is a licensed prescription medicine for the treatment of patients with PDR and, or, DME. LUCENTIS® is specifically designed to block new blood vessel growth in the eye, and so in turn can help to stop leakage and vision loss.

[Section 2 – what is PDR and DME?]

This section takes a closer look at PDR and visual impairment due to DME.

Diabetic retinopathy, or DR, is a common eye condition caused by diabetes that is classified as either non-proliferative DR, which is early-stage disease, or proliferative DR, which is end-stage disease. PDR can severely threaten vision, particularly in the later stages.

DME is an additional complication of diabetes that may accompany any stage of DR. This condition can also cause vision problems. Uncontrolled high blood sugar levels can damage the blood vessels in the retina, the light-sensitive part in the back of your eye that gathers images. DME occurs when blood vessels in the macula are affected. The macula is the small indent on the retina that helps you see fine details.

PDR and DME can develop in anyone who has type 1 or type 2 diabetes. The longer you have diabetes, and the less controlled your blood sugar level is, the more likely you are to develop these eye conditions.

Changes in the eye due to PDR and, or, DME that are treated with LUCENTIS® can include abnormal blood vessel growth, leakage of fluid from blood vessels, weakened and bulging blood vessels, also called microaneurysms, and rupture of blood vessels, also called hemorrhages.

[Section 3 – how are retinal diseases diagnosed?]

Next, let's discuss how retinal diseases are 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: those examining eye function include techniques that assess vision, such as vision charts; and those examining eye structure include techniques that examine the tissues of the eye for damage or disease.

As well as the standard tests, such as vision charts and examination of the eye with a handheld device, additional techniques are employed to examine eye blood vessels and tissues.

Fluorescein angiography is a technique used to visualize the blood vessels at the back of the eye. During a fluorescein angiography exam, the doctor will first 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 then taken.

Optical coherence tomography, or OCT, is a commonly used technique that produces cross-sectional images of the back of the eye. This is a non-invasive technique that just requires you to keep your head still and look into a machine while detailed images of your retina are taken without needing to touch your eye.

[Section 4 – how is LUCENTIS® treatment given?]

Next, let's talk about how LUCENTIS® treatment is given.

LUCENTIS® is given by your ophthalmologist, or eye doctor, as an injection into the eye. It's normal to worry about such injections, but patients have reported that most often the injection is virtually painless and sounds worse than it is. The majority of patients reported that any apprehensions about injections dissipated after the first 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, such as weakness or paralysis of limbs or face, or 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 and clean your eye and the skin around it. Then your eye will be held open so you don't blink, and numbed 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's important to tell your doctor if you have an eye infection or any pain or redness in your eye, or if you think you may be allergic to LUCENTIS® or to Betadine®, which is another name for iodine.

[Section 5 – after treatment]

Now let's talk about what will happen after you receive your LUCENTIS® injection.

After you receive your LUCENTIS® injection, your doctor will perform eye tests, such as measuring the pressure in your eye, to make sure that the treatment went well. The white area of the eye, where the injection was given, will likely be red. This redness is normal and it will go away in a few days. Contact your doctor if it doesn't 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 don't 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, 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 or tearing; swollen lids or other swelling; increasing redness; blurred or distorted vision, or sudden vision loss; light flashes; seeing flies, black spots, or colored halos; or drying of the surface of your eye.

If you notice any side effects not mentioned, tell your doctor or pharmacist.

Now, let's talk about how long you will need to continue treatment with LUCENTIS®.

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 with your doctor about your results and your feelings about your treatment.

It is important to keep attending your eye doctor appointments as the best way to protect your independent lifestyle and your vision is to visit your doctor on a regular basis. Be sure to 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, and follow your doctor's instructions carefully as they may differ from the information provided here.

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.

Finally, let's talk about what you can do to help improve your visual impairment.

It is important that you 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's 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 don't have family or friends who can help, ask at your doctor's office about support services.

Take care of your diabetes. High blood sugar levels make it more likely for PDR and DME to get worse and increase the risk of visual impairment due to DME. Controlling your blood sugar levels is an important part of maintaining your vision and getting the most out of your treatment. There are many things that you and your healthcare team can do to manage your diabetes. Regularly monitor your blood sugar levels as instructed by your doctor. Take your medication as directed. Taking all of your medications correctly – both for diabetes and for your PDR and, or, visual impairment due to DME – will give you the best results. Manage your diet with your healthcare team. Your doctor can tell you what you should and shouldn't eat, and when you should eat. Also, adjust your lifestyle. You should eat a balanced diet because it is good for your body and overall health, which is, in turn, good for your eyes.

We hope this information has helped you to better understand PDR and DME, and treatment with LUCENTIS®.

Keep this CD; you may need to listen to 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 mentioned on this CD, please tell your doctor.

Suspected adverse reactions and medication errors associated with the use of Lucentis should be reported to: Malta Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000. Or at: www.medicinesauthority.gov.mt/adrportal.

Alternatively at: Novartis Pharma Services Inc., Representative Office, Malta by phone on +356 21222872.

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