

# Your guide to therapy with Lucentis<sup>®</sup> (ranibizumab) for the treatment of proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular edema (DME)

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This booklet has been created to help you better understand Lucentis when used for the treatment of proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular edema (DME)

## What is Lucentis?

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- In PDR and DME, damage to the retina (the light-sensitive layer at the back of the eye) results from the abnormal growth of new, leaky blood vessels<sup>1,2</sup>
- In DME, vision loss is predominantly caused by macular edema (swelling of the center of the retina)<sup>2,3</sup>
- Lucentis is a licensed prescription medicine for the treatment of patients with PDR and/or DME<sup>4</sup>
- 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<sup>5</sup>

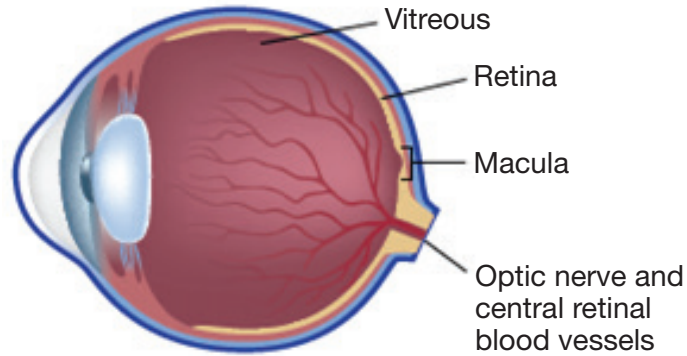
### What is proliferative diabetic retinopathy (PDR) and diabetic macular edema (DME)?

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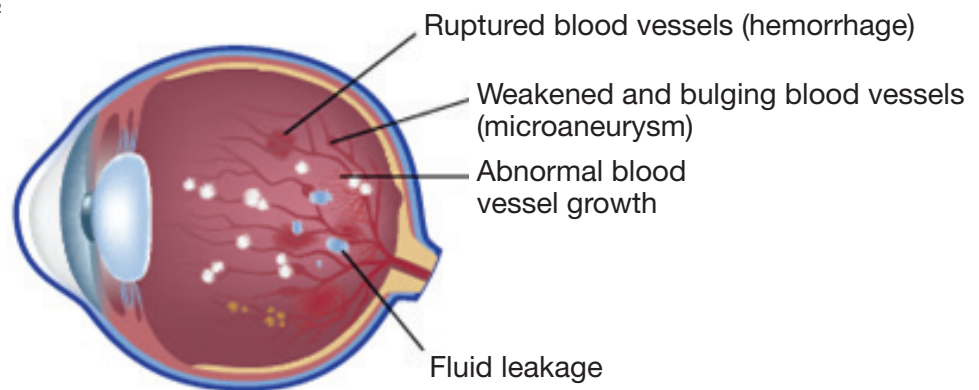
- Diabetic retinopathy (DR) is a common eye condition caused by diabetes that is classified as either non-proliferative DR (early-stage disease) or proliferative DR (end-stage disease).<sup>3</sup> PDR can severely threaten vision, particularly in the later stages<sup>3</sup>
- DME is an additional complication of diabetes that may accompany any stage of DR.<sup>3</sup> This condition can also cause vision problems.<sup>6</sup> Uncontrolled high blood sugar levels can damage the blood vessels in the retina,<sup>7</sup> the light-sensitive part in the back of your eye.<sup>2</sup> DME occurs when blood vessels in the macula are affected.<sup>6</sup> The macula is the small indent on the retina that helps you see fine details<sup>8</sup>
- PDR and DME can develop in anyone who has type 1 or type 2 diabetes.<sup>2,6</sup> The longer you have diabetes, and the less controlled your blood sugar level is, the more likely you are to develop these eye conditions<sup>6</sup>
- Changes in the eye due to PDR and/or DME that are treated with Lucentis can include:<sup>6</sup>
  - > Abnormal growth of blood vessels
  - > Leakage of fluid from blood vessels
  - > Weakened and bulging blood vessels (microaneurysms)
  - > Rupture of blood vessels (hemorrhages)

# Section 2 – What is proliferative diabetic retinopathy (PDR) and diabetic macular edema (DME)?

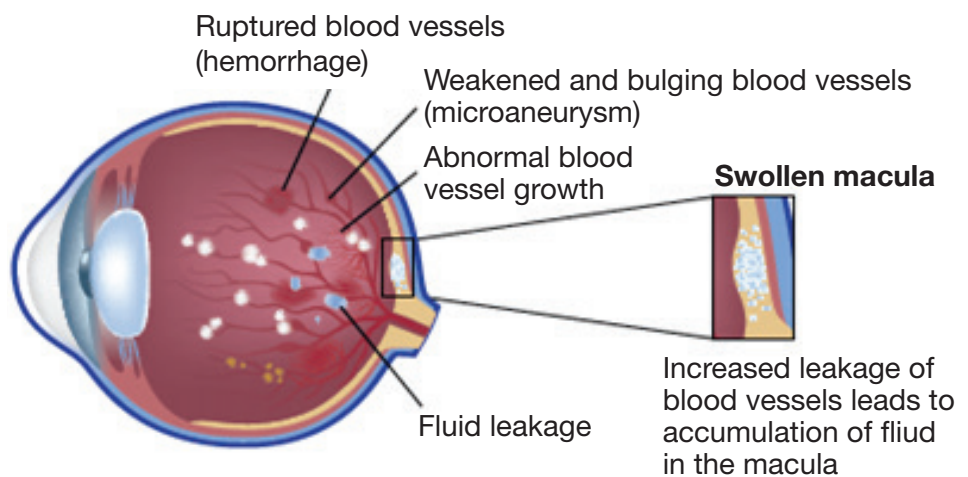
## Healthy eye<sup>1</sup>



## Eye with PDR<sup>2</sup>



## Eye with PDR and DME<sup>2</sup>



## How are retinal diseases diagnosed?

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- There is a range of different techniques used to examine the eye
- As well as the standard tests (vision charts, examination of the eye with a handheld device, etc.),<sup>6,9</sup> additional techniques are employed to examine eye blood vessels and tissues<sup>6</sup>
- **Fluorescein angiography (FA)** is a technique used to visualize the blood vessels at the back of the eye<sup>9,10</sup>
- **Optical coherence tomography (OCT)** is a commonly used technique that produces cross-sectional images of the back of the eye<sup>6,10,11</sup>

## How is Lucentis treatment given?

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- Lucentis is given by your ophthalmologist (eye doctor) as an injection into the eye

### **What will happen at my appointment?**

- 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's important to tell your doctor if you:
  - > Have an infection in or around the eye
  - > Have any pain or redness in your eye
  - > Think you may be allergic to Lucentis or to iodine

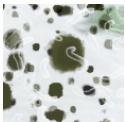
## What to expect after treatment?

### After injections into the eye such as Lucentis, the following events may occur:

- Injections into the eye may cause an infection such as an uncommon serious infection of the eyeball (endophthalmitis)
- Inflammation in the eye (intraocular inflammation)
- Retinal detachment/tear may occur sometimes after Lucentis treatment, this is a serious common side effect
- Temporary increase in eye pressure (intraocular pressure). 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 don’t go away or if they get worse as they can indicate regarding retinal detachment or tear
- Clouding of the lens (cataract). This is a serious common side effect
- Contact your doctor as soon as possible if you have any of the following signs and symptoms in your eye or if they get worse as they can indicate regarding retinal detachment or tear, increased intraocular pressure, intraocular inflammation or endophthalmitis:



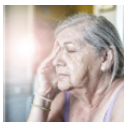
Blurred, distorted or sudden loss of vision



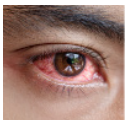
Seeing floaters/flying flies, black spots or colored halos



Pain, Drying of the surface of your eye, Swollen lids or other swelling



Light flashes or Light sensitivity/tearing



Increasing redness or worsening of eye redness

## What can I do after my treatment?

- 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 or use machines 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
- If you notice any side effects not listed in this leaflet, tell your doctor or pharmacist

**Adverse events can be reported  
to the Ministry of Health via  
<https://sideeffects.health.gov.il>**

**You may also report to the registration  
holder, Novartis Israel LTD. at:  
[safetydesk.israel@novartis.com](mailto:safetydesk.israel@novartis.com)**

## 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 with 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**
  - > **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
- For further information and prior to use of the product, please read the Patient Information Leaflet inside the package
- Follow all your doctor's instructions carefully. They may differ from the general information in this booklet

**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'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<sup>12,13</sup>
  - > Controlling your blood sugar levels is an important part of maintaining your vision and getting the most out of your treatment<sup>13</sup>
- **There are many things you and your healthcare team can do to manage your diabetes**
  - > Regularly monitor your blood sugar levels as instructed by your doctor<sup>13</sup>
  - > Take your medicinal treatment as directed.<sup>12</sup> 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.<sup>12,14</sup> Your doctor can tell you what you should and should not eat and when you should eat
- **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<sup>12,14</sup>

**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.  
Adverse events can be reported to the Ministry of Health via <https://sideeffects.health.gov.il>  
You may also report to the registration holder, **Novartis Israel LTD. at: [safetydesk.israel@novartis.com](mailto:safetydesk.israel@novartis.com)****

This booklet, format and content have been approved by the Ministry of Health on October 2024.

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#### **Illustrations:**

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