

Important safety information for patients treated with Lucentis[®] (ranibizumab) for proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular edema (DME)

**This document is approved by
Saudi Food and Drug authority**

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)

If you experience any of the following symptoms please contact your Doctor:

DME

- 1. Blurry vision**
- 2. Floaters**
- 3. Double vision**
- 4. Eventually blindness**

PDR

- 1. Spots or dark strings floating**
- 2. Blurred vision**
- 3. Fluctuant vision**
- 4. Impaired color vision**
- 5. Dark or empty areas**

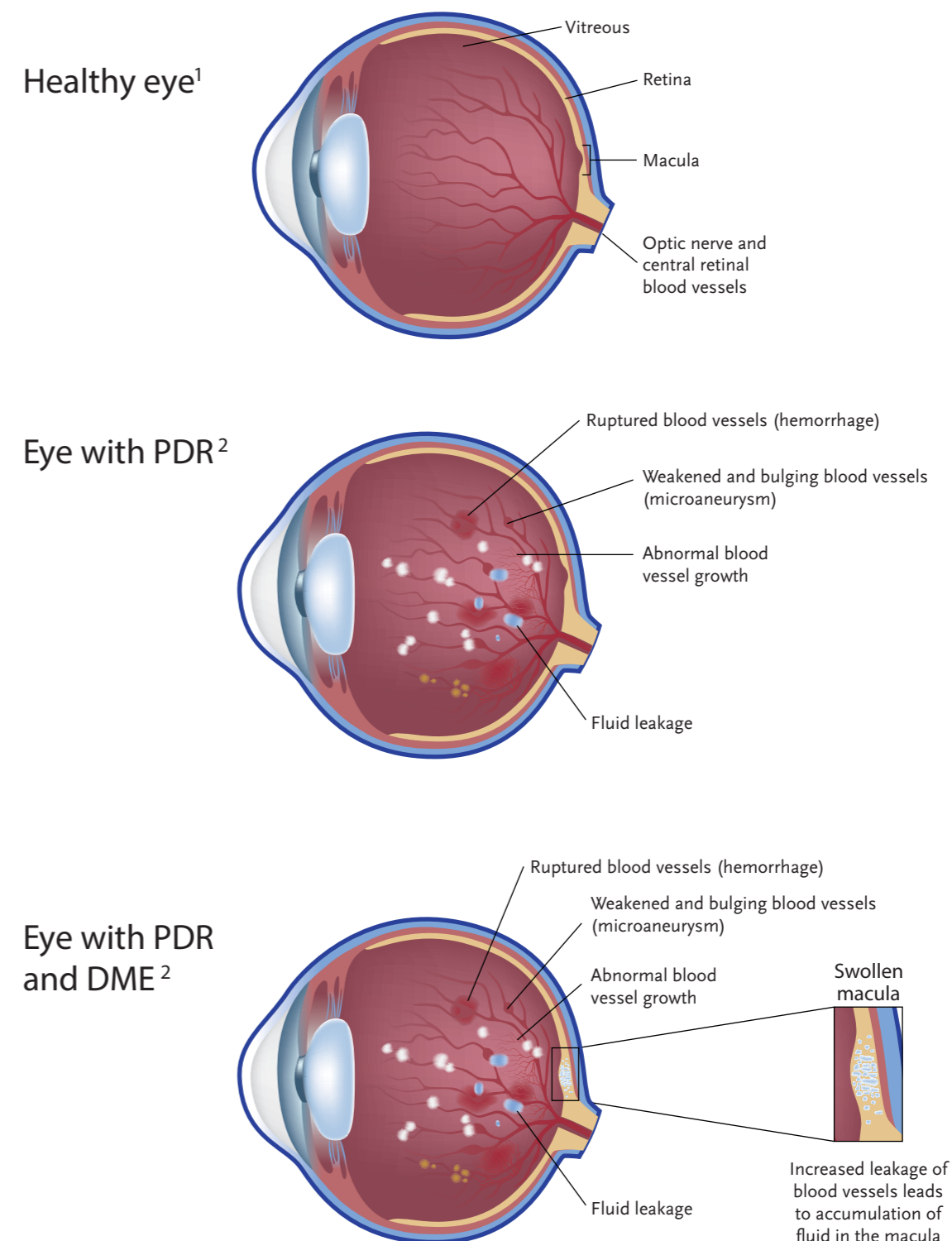
WHAT IS LUCENTIS®?

- 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^{1,2}
- In DME, vision loss is predominantly caused by macular edema (swelling of the center of the retina)^{2,3}
- Lucentis® is a licensed prescription medicine for the treatment of patients with PDR and/or DME⁴
- Lucentis® is specifically designed to block new blood vessel growth in the eye, and so in turn can help to stop leakage and vision loss⁵

¹.Watkins PJ. *BMJ*. 926-924 :(7395)326 ;2003; ². National Eye Institute. Available: <https://nei.nih.gov/health/diabetic/retinopathy> [accessed October 2019]; ³.Gucciardo E, *et al. Int J Mol Sci*. 4034 :(12)19 ;2018; ⁴. Lucentis® Summary of Product Characteristics. Novartis Pharma AG. https://www.ema.europa.eu/en/documents/product-information/lucentis-epar-product-information_en.pdf; ⁵. Ferrara N, *et al. Retina*. 870-859 :(8)26 ;2006.

WHAT IS PROLIFERATIVE DIABETIC RETINOPATHY (PDR) AND DIABETIC MACULAR EDEMA (DME)?

- 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).¹ PDR can severely threaten vision, particularly in the later stages¹
- DME is an additional complication of diabetes that may accompany any stage of DR.¹ This condition can also cause vision problems.² Uncontrolled high blood sugar levels can damage the blood vessels in the retina,³ the light-sensitive part in the back of your eye that gathers images.⁴ DME occurs when blood vessels in the macula are affected.² The macula is the small indent on the retina that helps you see fine details⁵
- PDR and DME can develop in anyone who has type 1 or type 2 diabetes.^{2,4} The longer you have diabetes, and the less controlled your blood sugar level is, the more likely you are to develop these eye conditions²
- Changes in the eye due to PDR and/or DME that are treated with Lucentis can include:²
 - > Abnormal blood vessel growth
 - > Leakage of fluid from blood vessels
 - > Weakened and bulging blood vessels (microaneurysms)
 - > Rupture of blood vessels (hemorrhages)



1. Gucciardo E, *et al.* *Int J Mol Sci.* 2018; 19(12): 4034; 2. American Academy of Ophthalmology. Available: <https://www.aao.org/Assets/9f2de0c1-1c30-442f-a3bb-c76e2cf19502/636492239481630000/final-diabetic-retinopathy-update-2017-pdf> [accessed October 2019]; 3. Melmed S, *et al.* *Williams Textbook of Endocrinology* 12th Edition, 2011, Chapter 33. Published by Saunders (ISBN: 9781437703245); 4. National Eye Institute. Available: <https://nei.nih.gov/health/diabetic/retinopathy> [accessed October 2019]; 5. Jager RD, *et al.* *N Engl J Med.* 2008; 358(24): 2606-2617.

1. American Academy of Ophthalmology. Available: <https://www.aao.org/eye-health/diseases/what-is-diabetic-retinopathy> [accessed October 2019]; 2. American Academy of Ophthalmology. Available: <https://www.aao.org/Assets/9f2de0c1-1c30-442f-a3bb-c76e2cf19502/636492239481630000/final-diabetic-retinopathy-update-2017-pdf> [accessed October 2019].

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 handheld device, etc.),^{1,2} additional techniques are employed to examine eye blood vessels and tissues²
- **Fluorescein angiography** 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** is a commonly used technique that produces cross-sectional images of the back of the eye^{2,4}
 - > This is a non-invasive technique⁴ 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

1. Lueck CJ, et al. *J Neurol Neurosurg Psychiatry*. 2004; 75(Suppl 4): iv2-iv11; 2. American Academy of Ophthalmology. Available: <https://www.aao.org/Assets/9f2de0c1-1c30-442f-a3bb-c76e2cf19502/636492239481630000/final-diabetic-retinopathy-update-2017-pdf> [accessed October 2019]; 3. Arias L, Mones J. AMD Book: Fluorescein angiography. Available: <http://www.amdbook.org/content/fluorescein-angiography-0> [accessed October 2019]; 4. Huang D, et al. *Science*. 1991; 254(5035): 1178-1181.

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 is¹
 - > The majority of patients reported that any apprehensions about injections dissipated after the first injection¹

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's 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 to 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 for 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/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 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
- 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'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^{1,2}
 - > Controlling your blood sugar levels is an important part of maintaining your vision and getting the most out of your treatment²
- 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 doctor²
 - > Take your medication as directed.¹ 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.^{1,3} 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^{1,3}

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

1. American Academy of Ophthalmology. Available: www.aao.org/Assets/dba38b76-3095-4360-8cb6-00adab3aad68/635919125497230000/diabetic-retinopathy-ppp-pdf [accessed October 2019]; 2. Diabetes Control and Complications Trial Research Group. *N Engl J Med.* 1993; 329(14): 977-986; 3. Chew EY, et al. *Arch Ophthalmol.* 1996; 114(9): 1079-1084.

You can report any problem or adverse events or request additional copies of the materials through:
Patient Safety Department Novartis Pharma AG - Saudi Arabia
-.
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: <http://report.novartis.com/>

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Fax: +966112057662
Email: npc.drug@sfd.gov.sa
Or by online: <https://ade.sfda.gov.sa>

يمكنك الإبلاغ عن أي أعراض جانبية أو شكاوى أو لطلب نسخ إضافية من خلال:
شركة نوفارتس - السعودية - قسم سلامة المرضى
الرقم المجاني: 8001240078
الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠
الفاكس: ٠٠٩٦٦١١٢٦٥٨١٠٧
الايمل: adverse.events@novartis.com
او عن طريق الانترنت: <http://report.novartis.com>

الهيئة العامة للغذاء والدواء، المركز الوطني للتيقظ الدوائي
مركز الاتصال الموحد: 19999
الفاكس: ٠٠٩٦٦١١٢٠٥٧٦٦٢
الايمل: npc.drug@sfd.gov.sa
او عن طريق الانترنت: <http://ade.sfda.gov.sa>

This document has been approved by Saudi Food and Drug Authority (SFDA).

هذا الملف تم إيماده من قبل الهيئة العامة للغذاء والدواء في السعودية