STADA



XIMLUCI®
ranibizumab

This Guide for Treatment with Ximluci® (Ranibizumab)

Version 1, August 8, 2023

This document is approved by the Executive Directorate of Pharmacovigilance at the Saudi Food and Drug Authority.

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This guide is made up to
support you for better understanding of

Ximluci®

when used for the treatment of proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular oedema (DMO)

SUMMARY OF IMPORTANT SAFETY INFORMATION

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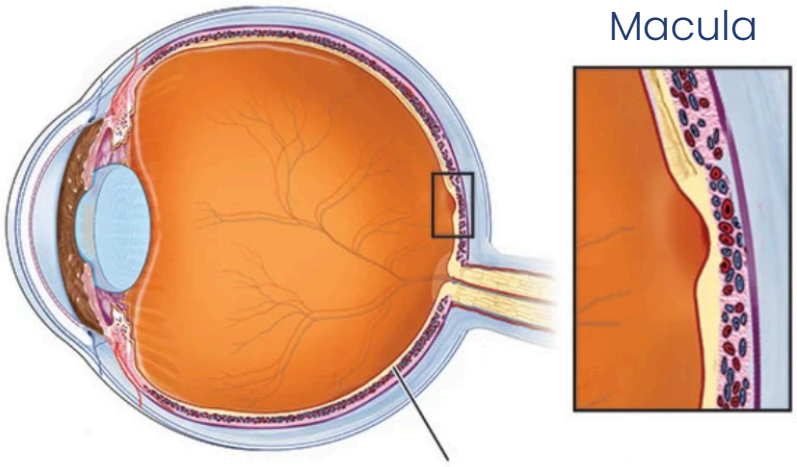
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What is Ximluci®?

- In diseases, such as **PDR and DMO,** abnormal blood vessels grow in the eye, which can leak and cause vision loss.[1]
- **Ximluci®** specifically recognizes and blocks the action of new blood vessel growth in the eye, and so in turn can help to stop leakage and vision loss.[1]



Healthy Eye



Healthy retina

References:
1. Ximluci. Summary of product characteristic.
2. Image: *Diabetes-Related Macular Edema.* (2023). Cleveland Clinic. https://my.clevelandclinic.org/health/diseases/24733-diabetes-related-macular-edema.

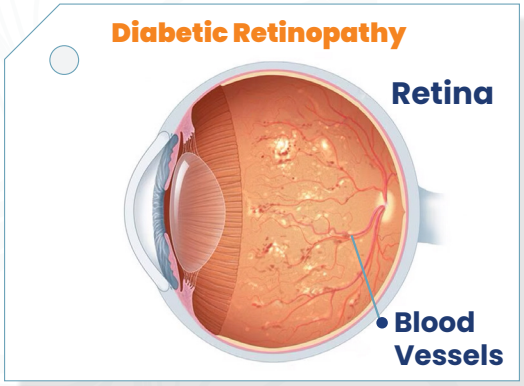
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What is Diabetic Retinopathy?

Diabetic retinopathy (DR) is a common eye condition caused by diabetes.[1]

- DR is classified as either non-proliferative DR (early-stage disease) or proliferative DR (end stage disease in which **abnormal new blood vessels** grow in the retina).[1]
- Proliferative diabetic retinopathy (PDR) can severely threaten your vision, particularly in the later stages.[1]

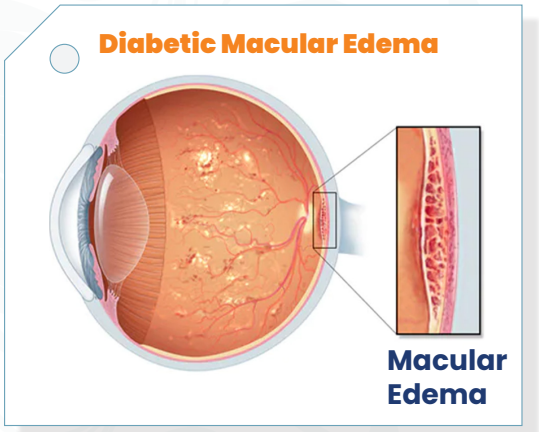


What is Diabetic Macular Oedema?

Diabetic macular oedema (DMO) is a condition that affects the **macula**, a part of the retina at the back of the eye.[1,2]

The macula is the area that lets you see sharply in the centre of your vision.[2]

- In patients with diabetes, having high blood sugar for a long time may cause damage to blood vessels in the eye.[3]
- Damaged blood vessels leak into the retina and the accumulation of this fluid causes damage to the retina and vision loss.[1,3]



In some cases, abnormal new blood vessels also start to grow under the macula, which may contribute to your vision loss.[1]

References:

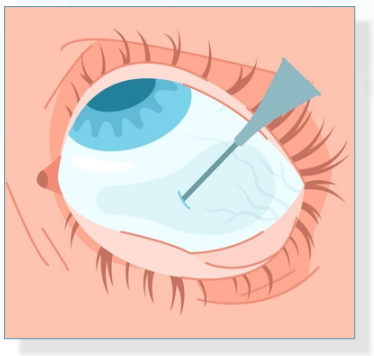
1. Gucciardo E, et al. *Int J Mol Sci.* 2018; 19(12): 4034. 2. Image: *Diabetic retinopathy - Symptoms & causes - Mayo Clinic.* (2023). Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/symptoms-causes/syc-20371611.
2. American Academy of Ophthalmology. Available http://one.aao.org/Assets/1c241e10-4be4-4a87-81fbae406e7a9e5f/635479433437730000/diabetic-retinopathy-pdf [accessed October 2016]. 2. Jager RD, et al. *N Engl J Med.* 2008;358(24):2606-17. 3. Melmed S, et al. *Williams Textbook of Endocrinology 12th Edition,* 2011, Chapter 33. Published by Saunders (ISBN: 9781437703245). 4. Image: *Diabetic macular edema.* (2023). Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/multimedia/diabetic-macular-edema/img-2012455.

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How is Ximluci® Treatment Given?

Ximluci® is given by your ophthalmologist **(Eye Doctor)** as an injection into the eye.[1]



- It is normal to worry about such injections, but usually the injection is **virtually painless**.[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 Ximluci®, it is important to tell your doctor if:**[1]
  - You have had a stroke or experienced transient signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding)
  - You are taking or have recently taken any other medicines, including medicines obtained without prescription
  - You have an eye infection
  - You have any pain or redness in your eye
  - You think you may be allergic to Ximluci® or to Betadine® (iodine)

Keeping your doctor informed will help them to decide whether **Ximluci®** is the **most appropriate treatment** for you.[1]

Reference:

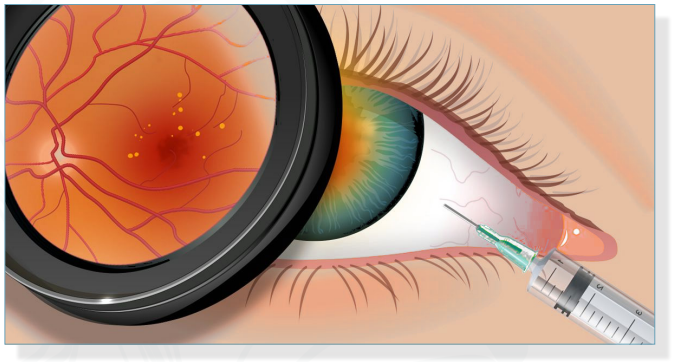
1. Ximluci. Summary of product characteristic.

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A doctor or nurse will:[1]

1. Cover your face and the area around the eye with a special drape
2. Clean your eye and the skin around it
3. Hold your eye open so you do not blink
4. Numb your eye with an anesthetic to prevent pain



5. The doctor will then give the injection into the white part of your eye (You may feel a little pressure with the injection).

What Will Happen After I Receive my Ximluci® Injection?

- Your doctor will perform eye tests, such as measuring the pressure in your eye, to make sure the treatment went well.[1]
- The white area of the eye, where the injection is given, will likely be red.[1]
  - » The redness is normal and it will go away in a few days.[1]
- You may see a few spots or 'floaters' in your vision.[1]
  - » These spots are normal and should go away in a few days.[1]
- 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.[1]
- You should not drive until your vision has returned to normal.[1]
- Rarely, injections in the eye can cause infection.[1]

It is important to monitor any changes in the condition of your eye and your overall well-being in the week following your injection.[1]

Please contact your doctor if either of these symptoms does not go away or gets worse.[1]

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1. Ximluci. Summary of product characteristic.

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How Long Will I Need to Continue Ximluci® Treatment?

- Every patient is **different**. It is likely that you will need additional **Ximluci®** injections, but this will depend on how you respond to treatment and how your vision changes.[1]
- If you are considering stopping treatment with **Ximluci®**, ask your doctor for advice first.[1]
- Your doctor will decide how often they wish to see you to monitor your condition and determine if you need additional injections.[1]
- Always go to every appointment that your doctor arranges for you.[1]
- If you miss an appointment for **Ximluci®** treatment, contact your doctor **as soon as possible**.[1]
- If you have any further questions, ask your doctor or pharmacist.[1]

When to Seek Care?

Please 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
- Light flashes
- Seeing flies, black spots, or colored halos
- Drying the surface of your eye
- Increasing redness
- Blurred, distorted, or sudden loss of vision



If you notice any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

References:

1. Ximluci. Summary of product characteristic.

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This guide is provided for your education and complements the Patient Information Leaflet.

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

You can report any problem or adverse events through:

Saudi Food and Drug Authority National Pharmacovigilance Center
SFDA call center: 19999
E-mail: npc.drug@sfda.gov.sa Or

STADA MENA DWC
Saudi Arabia, Riyadh, Olaya District
E-mail: PV.KSA@stada.com

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