

Your guide to therapy with Lucentis® (ranibizumab) for visual impairment due to diabetic macular edema (DME)



SECTION 1 – ABOUT LUCENTIS®

This booklet was created to help you better understand Lucentis®, a treatment for visual impairment due to diabetic macular edema (DME)

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 can affect vision, 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's normal to worry about such injections, but most patients say that the injection is painless and sounds worse than it really is

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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
- 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 anaesthetic 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)

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
- 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
 - If you usually drive, you should not drive until your vision has returned to normal

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†Betadine is a registered trademark of Mundipharma AG.

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

- It is important to monitor for 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 coloured
 halos; or drying of the surface of your eye
- Also, contact your doctor as soon as possible if you notice any of these other signs and symptoms: sudden pain or swelling in your muscles; headache; dizziness; shortness of breath; cough; nausea; vomiting; sweating; itchiness; skin rash; lip or facial swelling; limping that comes and goes; warmth/tenderness of the calf; numbness and pain of your skin, arms, or legs; nosebleed; bloody urine; bruising; slurred speech; or weakness or paralysis of muscles (especially to one side)

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

- Every patient is different. You will need ongoing treatment with Lucentis® depending on how your vision changes
- Talk with your doctor about your results and your feelings about your treatment
- If your vision doesn't 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

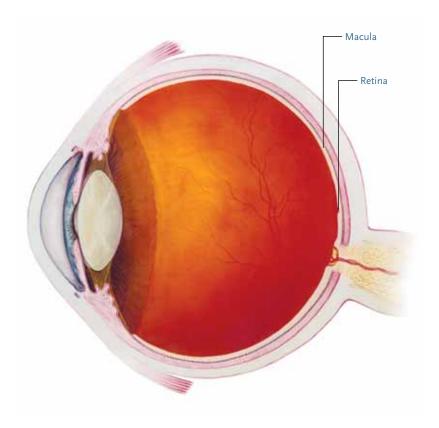
Your doctor will monitor the condition of your eye and, depending on how you respond to the treatment, will decide if and when you need to receive further treatment

Always go to every appointment that your doctor arranges for you

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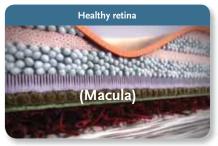
WHAT IS DME AND HOW DOES IT AFFECT MY VISION?

- DME is a complication of diabetes that affects the macula, a part of the retina at the back of the eye
 - The macula is the area that lets you see sharply in the centre of your vision



WHAT IS DME AND HOW DOES IT AFFECT MY VISION? (cont'd)

 One of the contributing factors for DME is a substance called vascular endothelial growth factor A (VEGF-A), which causes leakage and thickening in the layers of your retina that damage your vision





- It may be that the visual impairment due to DME has already started to affect your ability to do everyday things like reading, shopping, and driving
- Most patients will need to see their doctor regularly for tests and treatment

National Eye Institute, National Institutes of Health

WHAT CAN I EXPECT FOLLOWING TREATMENT WITH LUCENTIS®?

- With Lucentis®, for almost all patients, vision at least stays the same, and for many, it gets better
- Following treatment, some patients notice a difference in their vision in as early as one week
 - You may not notice an improvement right away, but it's important that you continue with regular treatment 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 DME, such as reading, shopping, and driving

WHAT CAN I DO TO HELP MY VISUAL IMPAIRMENT DUE TO DME?

- 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 increase the risk of visual impairment due to DME and make it more likely to get worse
 - Controlling your blood sugar levels is an important part of maintaining your vision and getting the most out of your treatment

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SECTION 2 – VISUAL IMPAIRMENT DUE TO DME

WHAT CAN I DO TO HELP MY VISUAL IMPAIRMENT DUE TO DME? (cont'd)

- There are many things you and your health care 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 visual impairment due to DME—will give you the best results
 - Manage your diet with your health care team.
 Your doctor can tell you what you should and shouldn't eat, and when you should eat

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

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