

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

This booklet was created to help you better understand Lucentis® when used for the treatment of the following condition:

- Proliferative diabetic retinopathy (PDR)
- Diabetic Macular Oedema (DMO)

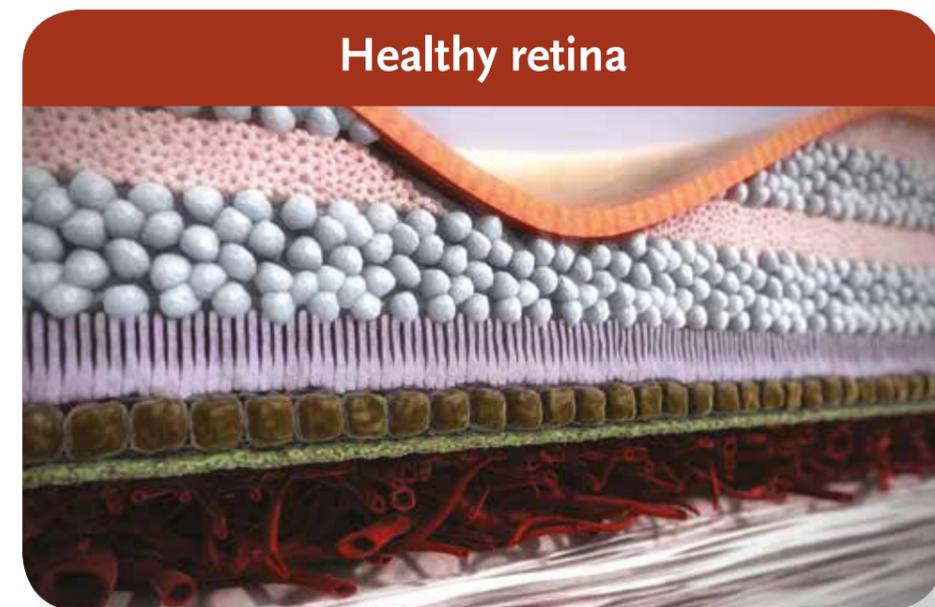
Summary of important safety information

Contact your doctor as soon as possible if you experience any of the following symptoms after treatment with Lucentis®:

- > Pain
- > Light sensitivity/tearing
- > Swollen lids or other swelling
- > Light flashes
- > Seeing flies, black spots or coloured halos
- > Drying of the surface of your eye
- > Increasing redness
- > Blurred, distorted or sudden loss of vision

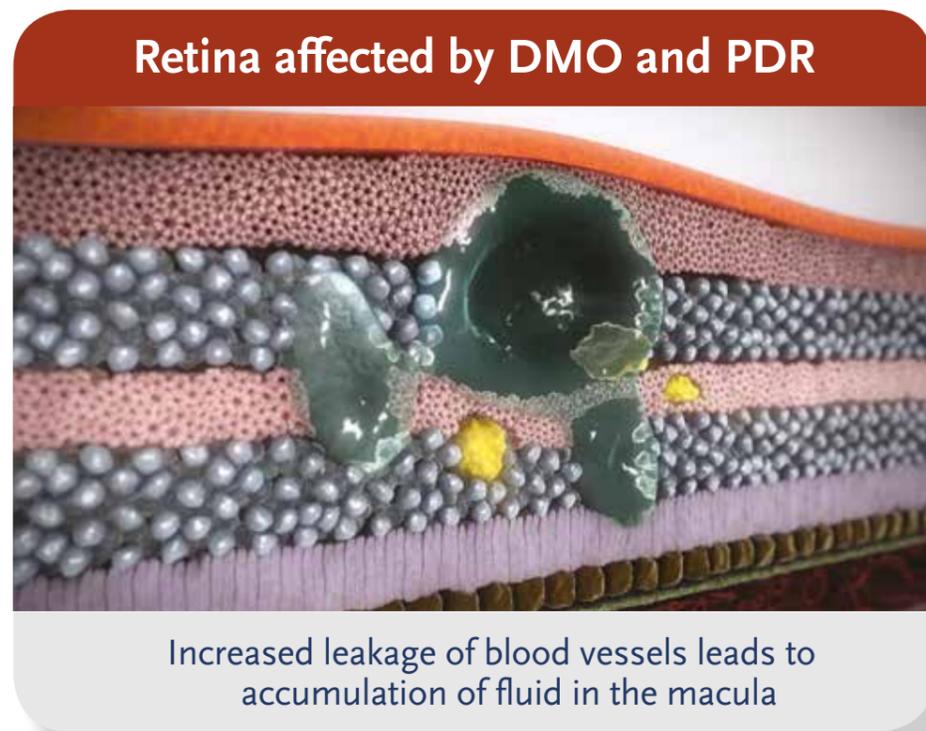
WHAT IS LUCENTIS®?

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



DMO

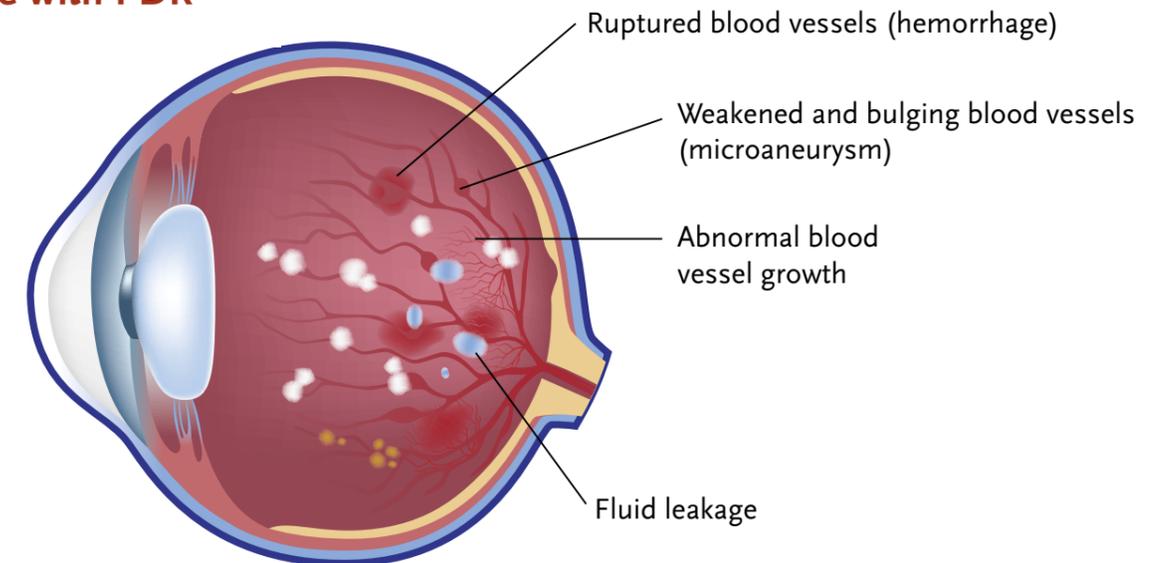
- DMO is a condition that affects the macula, a part of the retina at the back of the eye
- The macula is the area that lets you see sharply in the centre of your vision
- In patients with diabetes, having high blood sugar for a long time may cause damage to blood vessels in the eye. Damaged blood vessels leak into the retina and the accumulation of this fluid causes damage to the retina and vision loss
- In some cases, abnormal new blood vessels also start to grow under the macula, which may contribute to your loss of vision



PDR

- Diabetic retinopathy (DR) is a common eye condition caused by diabetes
- It 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)
- PDR can severely threaten vision, particularly in the later stages

Eye with PDR



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 usually the injection is virtually painless

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®, it is important to tell 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)
 - > 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 Lucentis® or to Betadine® (iodine)
- Keeping your doctor informed will help them to decide whether Lucentis® 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 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

AFTER TREATMENT

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
- 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 either of these symptoms 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 any changes in the condition of your eye and your overall well-being 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**
 - > **Swollen lids or other swelling**
 - > **Blurred, distorted or sudden loss of vision**
 - > **Light sensitivity/tearing**
 - > **Increasing redness**
 - > **Light flashes**
 - > **Seeing flies, black spots or coloured halos**
 - > **Drying of the surface of your eye**
- 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

SECTION 4 – AFTER TREATMENT

- You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard
- By reporting side effects you can help provide more information on the safety of this medicine.

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
- 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 advice 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

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

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