

**Important safety information  
for patients treated with**

# **RANIVISIO<sup>▼</sup>**

**(ranibizumab)**

**with proliferative diabetic retinopathy (PDR)  
and/or visual impairment due to diabetic  
macular edema (DME)**

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

**This guide has been created to help you better understand Ranivisio (ranibizumab) when used for the treatment of Proliferative diabetic retinopathy (PDR) and/or visual impairment due to Diabetic Macular Edema (DME)**



Please use the QR-Code or web address to access the audio format or to download this guide:

<https://medinfo.midas-pharma.com/ie>.

Please refer additionally to the Patient Information Leaflet to read what Ranivisio (ranibizumab) is and what it is used for.

If you find the Patient Information Leaflet difficult to read, it can be listened to or downloaded: <https://medinfo.midas-pharma.com/ie>.

## WHAT IS RANIVISIO?

In PDR and DME, damage to the retina (the light-sensitive layer at the back of the eye) result from the growth of new, abnormal leaky blood vessels.

In DME, vision loss is predominantly caused by macular edema (swelling of the center of the retina).

Ranivisio is a licenced prescription medicine for the treatment of patients with PDR and/or DME.

Ranivisio contains ranibizumab as the active medicinal ingredient.

Ranibizumab is specifically designed to block new vessel growth in the eye, and so in turn can help to stop leakage and vision loss.

## 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). PDR can severely threaten vision, particularly in the later stages.

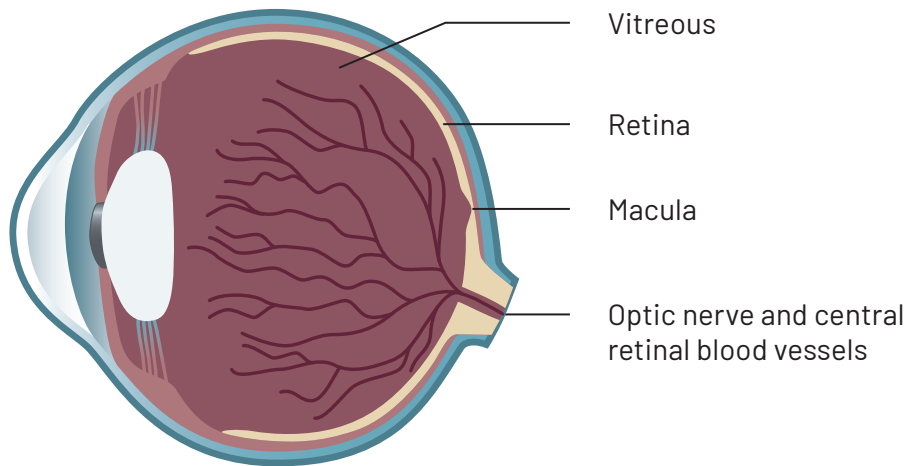
DME is an additional complication of diabetes that may accompany any stage of DR. This condition can also cause vision problems. Uncontrolled high blood sugar levels can damage the blood vessels in the retina, the light-sensitive part in the back of your eye that gathers images. DME occurs when blood vessels in the macula are affected. The macula is the small indent on the retina that helps you see fine details.

PDR and DME can develop in anyone who has type 1 or type 2 diabetes. The longer you have diabetes, and the less controlled your blood sugar level is, the more likely you are to develop these eye conditions.

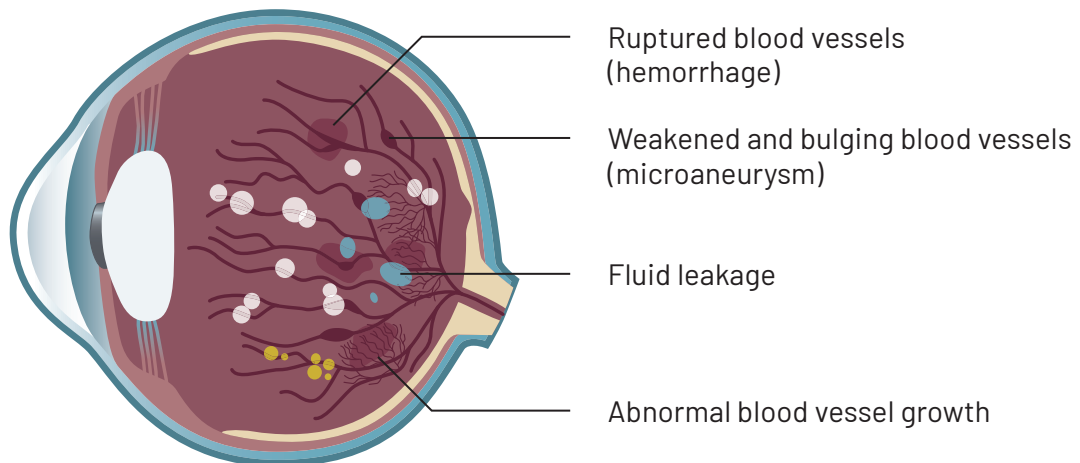
Changes in the eye due to PDR and/or DME that are treated with Ranivisio can include:

- Abnormal blood vessel growth.
- Leakage of fluid from blood vessels.
- Weakened and bulging blood vessels (microaneurysms).
- Rupture of blood vessels (hemorrhages).

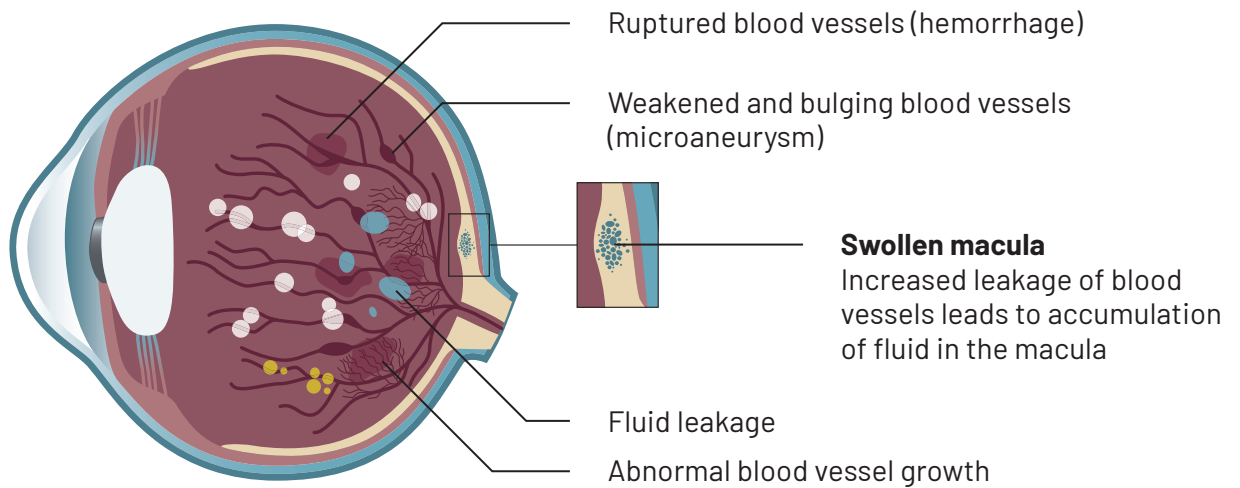
## Healthy eye



## Eye with PDR



## Eye with PDR and DME



## 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:

- 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.), additional techniques are employed to examine eye blood vessels and tissues.

**Fluorescein angiography** is a technique used to visualise the blood vessels at the back of the eye.

- 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.

- This is a non-invasive technique 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.

## HOW IS RANIVISIO TREATMENT GIVEN?

Ranivisio 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 is.

- The majority of patients reported that any apprehensions about injections dissipated after the first injection.

### What will happen at my treatment appointment?

On the day of your treatment, care will be taken to make sure you are relaxed and comfortable.

Before receiving Ranivisio, 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 do not 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 is 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 Ranivisio, to other medicines with ranibizumab or to Betadine® (iodine).

Keeping your doctor informed will help them to decide whether Ranivisio is the most appropriate treatment for you.

## WHAT WILL HAPPEN AFTER RECEIVED MY RANIVISIO 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 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.



## What to do if I have side effects?

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
- 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.

Please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

## How long will I need to continue Ranivisio treatment?

Every patient is different. It is likely that you will need additional Ranivisio injections, but this will depend on how you respond to treatment and how your vision changes.

Talk with your doctor about 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 Ranivisio, 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 guide.

- **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 Ranivisio (ranibizumab) 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.
- Controlling your blood sugar levels is an important part of maintaining your vision and getting the most out of your treatment.

### 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 doctor.
- Take your medication as directed. 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. 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.

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

**If you have any further questions, ask your doctor or pharmacist.**

**Please check on [www.medicines.ie](http://www.medicines.ie) for the most current version of the Patient Information leaflet and the Summary of Product Characteristics.**

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet.

You can also report side effect directly via HPRA Pharmacovigilance website:

[www.hpra.ie](http://www.hpra.ie)

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