

Important safety information  
for patients treated with

# RANIVISIO<sup>▼</sup>

(ranibizumab)

with visual impairment due to  
retinal vein occlusion (RVO)

- ▼ 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 was created to help you better understand Ranivisio (ranibizumab) when used for the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).**



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 branch and central RVO, vision loss predominantly results from damage to the blood vessels of the eye causing them to leak fluid. However, vision loss from the growth of new, abnormal blood vessels is also known in this condition.

Ranivisio contains ranibizumab as the active medicinal ingredient.

Ranibizumab specifically recognises and blocks the action of new blood vessel growth in the eye, and in turn can help to stop leakage and vision loss.

# WHY HAVE I BEEN PRESCRIBED RANIVISIO?

## You have been diagnosed with RVO.

RVO is a condition that affects the macula, a part of the retina at the back of the eye.

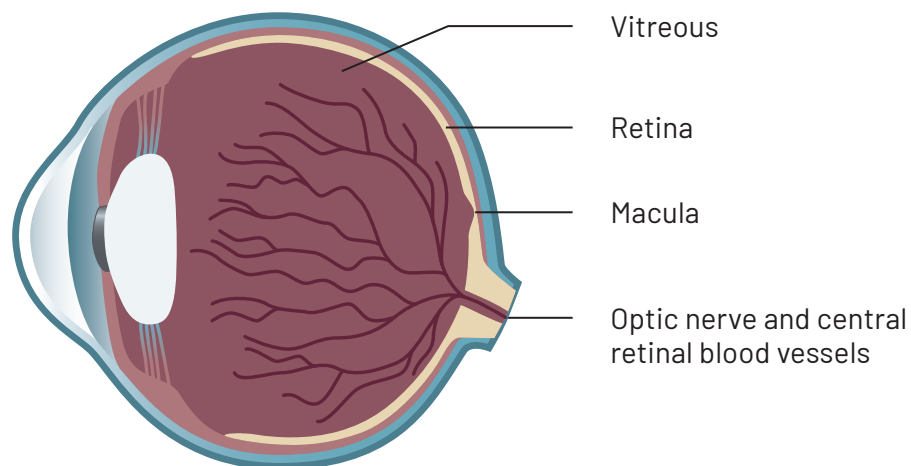
The macula is the area that lets you see sharply in the centre of your vision.

Blockage of a retinal vein can cause leakage of fluid into the retina and swelling of the macula. This may damage the retina and cause vision loss.

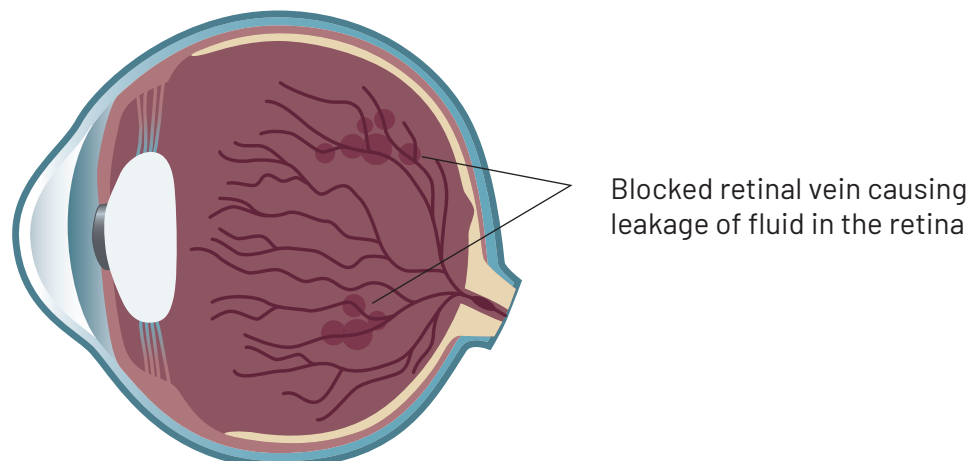
There are two types of RVO, central and branch, which are defined by the type of blood vessel that is affected:

- Branch RVO is more common than central RVO and is caused by obstruction of a tributary of the retinal vein. Only the part of the retina that is drained by the blocked branch is affected.
- Central RVO is caused by obstruction of the central retinal vein. Because the main vein in the eye is blocked, the entire retina is affected.

### Healthy eye



### Eye with RVO



## 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 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.

### 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 not listed in this leaflet, tell your doctor or pharmacist.

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 or other ranibizumab 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.

### 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.
- Limiting fatty and high-cholesterol foods may help avoid plaque build-up that could narrow your blood vessels.
- If you smoke, try to quit – smoking can damage blood vessels and harm your eyes.
- Get regular exercise – sufficient physical activity may help you maintain an ideal weight and keep your vascular system (blood vessels) healthy.

**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.