



Ranivisio

(ranibizumab 10 mg/ml)

Patient Guide

For neovascular (wet) age-related macular degeneration (AMD)

For visual impairment due to choroidal neovascularization (CNV)

For visual impairment due to macular edema secondary to retinal vein occlusion (RVO)

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

This guide contains general information regarding the treatment with **Ranivisio** and also detailed information about various eye diseases for which the treatment with **Ranivisio** can be suitable.

This guide was created to help you better understand **Ranivisio** (ranibizumab) when used for the treatment of the medical condition in your eye. **Ranivisio** is intended for the treatment of the following eye diseases:

- Neovascular (wet) age-related macular degeneration (AMD)
- Visual impairment due to choroidal neovascularization (growth of new, abnormal blood vessels in the vascular layer of the eye) (CNV)
- Visual impairment due to macular edema secondary to retinal vein occlusion (RVO)
- Proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular edema (DME)

In addition to the information in this guide, refer to the patient information leaflet enclosed in the **Ranivisio** packaging.

To view this guide, for more information about the preparation and for updated leaflets in Hebrew, Arabic and English, scan the following code:

Ranivisio



1. What is Ranivisio?

Ranivisio contains the active substance ranibizumab. Ranibizumab specifically recognizes and blocks the abnormal growth of new blood vessels in the eye, and in turn can help to stop leakage and vision loss.

Ranivisio is a bio-similar medicine. For further information about bio-similar medicines, refer to the Ministry of Health website:

<https://www.gov.it/he/Departments/General/biosimilar>

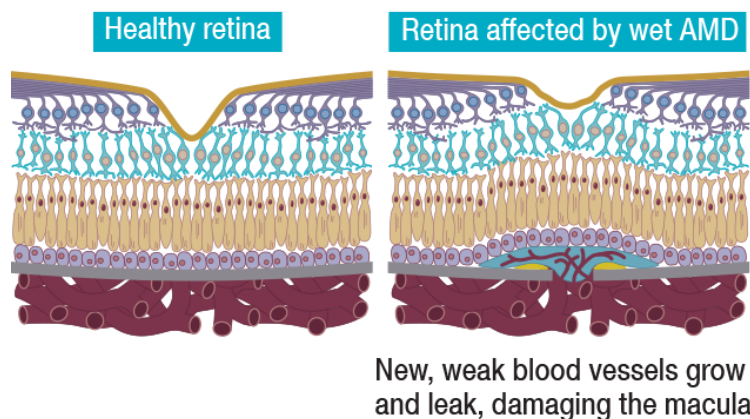
2. Why have I been prescribed Ranivisio?

Ranivisio is intended for the treatment of adults for several eye diseases that cause visual impairment. These diseases result from damage to the retina (a light-sensitive layer at the back of the eye), caused by the conditions that the medicine is intended to treat.

This chapter contains information about several eye diseases, please read the information carefully according to the diagnosis made by your eye doctor. If you are not sure about the medical diagnosis for which you have been prescribed Ranivisio, please contact your doctor or nurse.

Neovascular (wet) Age-related Macular Degeneration (AMD)

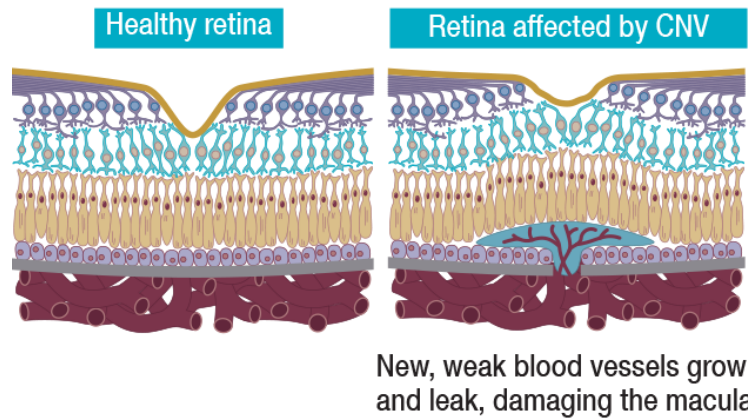
- Wet AMD is a condition that affects the macula, a part of the retina at the back of the eye.
- The macula is the area that lets you see sharply in the center of your vision.
- With age, and with the build-up of waste products, changes can occur in the retina.
- This can result in new, weak blood vessels growing and leaking under the macula, damaging your central vision.



Choroidal Neovascularization (CNV)

- CNV 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 center of your vision.
- CNV is the growth of new, weak blood vessels under the macula, which can leak fluid and blood into the retina, affecting your central vision.

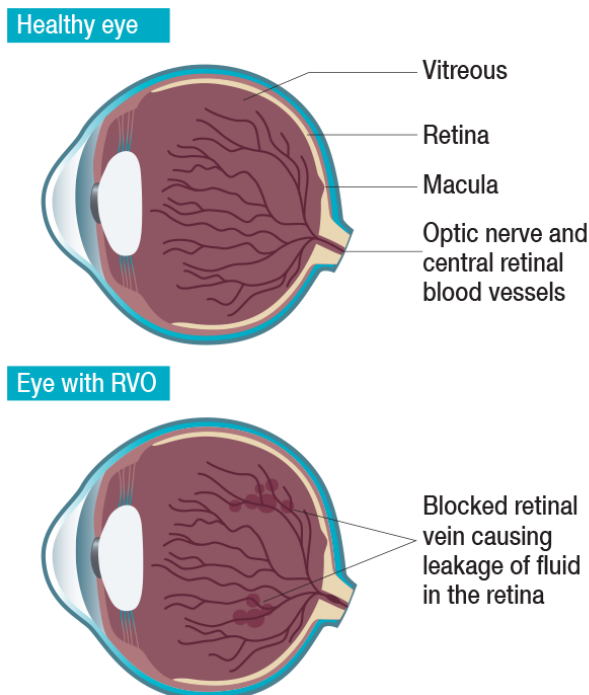
- CNV is observed in age-related macular degeneration (AMD); it may also be associated with other diseases. These include CNV due to pathologic myopia (PM), angioid streaks or central serous chorioretinopathy (CSC), and inflammatory CNV.



Retinal Vein Occlusion (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 center 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.



Proliferative Diabetic Retinopathy (PDR) and Diabetic Macular Edema (DME)

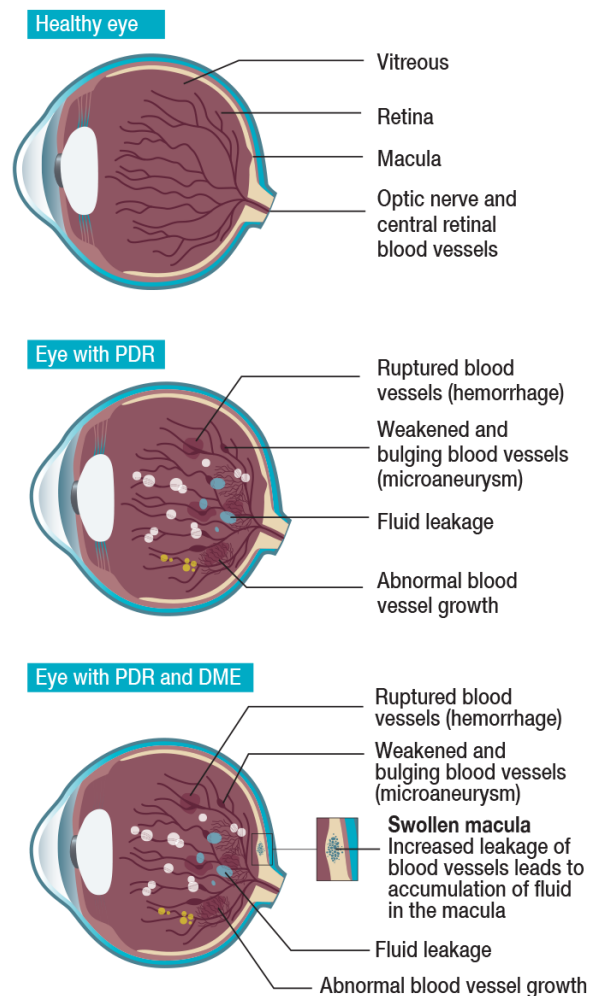
Diabetic retinopathy (DR) is a common eye condition caused by diabetes that is classified as either non-proliferative DR (early-stage disease) or proliferative DR (end-stage disease). PDR can severely threaten vision, particularly in the later stages.

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 Raniviso can include:

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



3. How are retinal diseases diagnosed?

There is a range of different techniques used to examine the eye. 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 visualize the blood vessels at the back of the eye.

Optical coherence tomography is a commonly used technique that produces cross sectional images of the back of the eye.

4. How is Ranivisio treatment given?

Ranivisio will be administered to you as a single injection into the eye by your eye doctor under local anaesthesia.

What will happen at my treatment appointment?

Before the **Ranivisio** treatment, 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 other medicines, including non-prescription medicines and nutritional supplements.

A doctor or nurse will perform the following actions:

- Cover your face and the area around the eye with a special drape.
- Clean your eye and 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 infection in or around the eye.
- Have any pain or redness in your eye.
- Think you may be allergic to **Ranivisio**, to other medicines with ranibizumab or to iodine.

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

5. What will happen after you received 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 the redness 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.

- Do 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 the injection.

Rarely, injections in the eye can cause infection.

What to do if I have side effects?

Ranivisio may cause side effects in the eye, such as:

- **Detachment or tear of the layer in the back of the eye (retinal detachment or tear)**
- **Infection of the eyeball (endophthalmitis) with inflammation of the inside of the eye**
- **Increased eye pressure**
- **Clouding of the lens (cataract)**

Refer to the doctor immediately if you have any of the following symptoms in your eye:

- **Pain or increased discomfort in the eye**
- **Worsening eye redness**
- **Blurred or decreased vision or sudden loss of vision**
- **Increased number of small particles in the field of vision**
- **Increased sensitivity to light/ tearing**
- **Swollen lids or other swelling**
- **Light flashes**

Please refer to the patient information leaflet for the complete list of side effects.

Reporting side effects

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this guide or the patient information leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

Additionally, you can report to the registration holder, Dexcel Ltd., by contacting customer service at the email address CustomerService@dexcel.com or by phone at 04-6364016.

How long will I need to continue Ranivisio treatment?

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

Talk with your doctor about the 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 medicine, 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.

Additionally, if you suffer from neovascular (wet) age-related macular degeneration (AMD):

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.
- Try to eat more leafy vegetables, fish, wholegrain foods and nuts (antioxidants).
- If you smoke, try to quit – smoking can damage blood vessels and harm your eyes.

Sunlight can damage your eyes, so wear sunglasses when you go out in bright sunlight.

Additionally, if you suffer from visual impairment due to macular edema secondary to retinal vein occlusion (RVO):

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.

- 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.

Additionally, if you suffer from proliferative diabetic retinopathy (PDR) and/or visual impairment due to diabetic macular edema (DME):

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.

<p>Keep this guide; you may need to read it again. If you have any further questions, ask your doctor or pharmacist.</p>

Approved by the Ministry of Health in September 2024.