PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRANOPTO™

Ranibizumab injection

Read this carefully before you start taking Ranopto and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Ranopto.

If you have difficulties with reading this document, ask someone for help with reading it.

Ranopto is a biosimilar biologic drug (biosimilar) to the reference biologic drug PrLucentis®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is Ranopto used for?

Ranopto is given as an injection into the eye by a healthcare professional under a local anesthetic.

Ranopto is used to treat damage to the retina (the light-sensitive back part of the eye) caused by growth of leaky abnormal blood vessels (choroidal neovascularization, CNV) in diseases that may cause decreased vision such as:

- Wet age-related macular degeneration (AMD),
- Diabetic macular edema (DME), or edema due to retinal vein occlusion (RVO), where fluid accumulates in the back of the eye, causing swelling (“edema”),
- CNV secondary to pathologic myopia (PM),
- CNV due to other causes.

How does Ranopto work?

The active substance in Ranopto is ranibizumab which is part of an antibody. Antibodies are proteins which specifically recognize and bind to other unique proteins in the body.

Ranibizumab binds selectively to all active forms of a protein called human vascular endothelial growth factor A (VEGF-A), which is present in the retina. Ranibizumab helps to stop the growth and leakage of new blood vessels in the eye, abnormal processes that contribute to several eye diseases that may cause decreased vision.

What are the ingredients in Ranopto?

Medicinal ingredient: ranibizumab.

Non-medicinal ingredients: α,α-trehalose dihydrate; histidine hydrochloride monohydrate; histidine; polysorbate 20; water for injection.

Ranopto contains no preservatives.

Ranopto comes in the following dosage form:

Vial:
Ranopto is a solution for injection supplied in a clear, colourless glass vial. The vial contains 0.23 mL of a sterile clear colourless to pale yellow solution.

Ranopto is supplied as a pack containing one glass vial of ranibizumab with chlorobutyl rubber stopper.

Do not use Ranopto if:

- you are allergic to ranibizumab or any of the other ingredients of Ranopto listed above. If you think you may be allergic, ask your healthcare professional for advice.
- you have already experienced an allergic reaction tell your healthcare professional before receiving Ranopto.
- you have or suspect you have an infection in or around your eye.
- you have pain or redness in your eye.

If any of these apply to you tell your healthcare professional. You should not be given Ranopto.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ranopto.

Take special care with Ranopto

- **Inform your healthcare professional if you have already had a stroke or experienced transient signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if Ranopto is the appropriate treatment for you.**
- Ranopto is given as an injection into the eye. Occasionally, an infection in the internal portion of the eye, pain or redness, detachment or tear of retina, or clouding of the lens may occur after Ranopto treatment. It is important to identify and treat such a type of infection or retinal detachment as soon as possible. **Please tell your healthcare professional immediately if you develop signs such as** eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light.
- In some patients the eye pressure may increase for a short period directly after the injection. There have also been reports of sustained eye pressure increases. This is something you may not notice; therefore, your healthcare professional should monitor this after each injection.
- Non-ocular hemorrhages have been reported after Ranopto treatment.

If you notice any changes after you have been given Ranopto, **please inform your healthcare professional immediately.**

BEFORE you receive Ranopto talk to your healthcare professional or pharmacist if:

- you are pregnant or planning to become pregnant. There is no clinical data on the use of Ranopto in pregnant women. Pregnancy should be avoided until at least three months after finishing Ranopto treatment. You should discuss with your healthcare professional the potential risk of Ranopto during pregnancy.
- you are using or plan to use birth control during treatment with Ranopto.
- you are breast-feeding. Ranopto is not recommended during breast-feeding because

Ranopto passes into human milk. Ask your healthcare professional or pharmacist for advice before Ranopto treatment.

The use of Ranopto in children and adolescents has not been studied and is therefore not recommended.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Ranopto:
No relevant interactions are known.

How to take Ranopto:

All Ranopto injections will be administered by your healthcare professional.

Follow your healthcare professional's instructions carefully.

If you are treated for wet age-related macular degeneration, the injection is given once a month in the first 3 months. Afterwards, your healthcare professional will continue to monitor your vision and the frequency of dosing can be between 1 and 3 months. Ranopto given every 3 months was not as effective as when given once a month.

If you are treated for visual loss due to diabetic macular edema or macular edema in RVO, the injection is given once a month. Your healthcare professional will monitor your vision monthly. If your vision remains the same while you are being given Ranopto treatment, your healthcare professional may decide to stop the treatment with Ranopto. Your healthcare professional will continue to monitor your vision monthly and will decide if treatment with Ranopto should be resumed or not. Your healthcare professional may decide that you also need to be treated with laser for these conditions, if so, laser treatment can be administered together with Ranopto.

If you are treated for visual loss due to CNV secondary to PM, the treatment is started with one injection of Ranopto. Your healthcare professional will continue to monitor the condition of your eye. Depending on how you respond to the treatment, your healthcare professional will decide whether and when you need to receive the next injection of Ranopto.

If you are treated for visual loss due to CNV, the treatment is started with one injection of Ranopto. Your healthcare professional will continue to monitor frequently the condition of your eye. Depending on how you respond to the treatment, your healthcare professional will decide whether and when you need to receive the next injection of Ranopto.

Before the injection, your healthcare professional will use a topical agent that kills germs or wash your eye carefully to prevent infection. Your healthcare professional will also give you a local anesthetic to reduce or prevent any pain you might have with the injection.

If you have further questions on the use of this product, ask your healthcare professional

Usual dose:
Ranopto (ranibizumab injection) is given as a single injection into your eye. The usual dose is 0.05 mL (which contains 0.5 mg of medicine). The time between two doses injected into the same eye should not be shorter than one month.

Older people (age 65 years and over): Elderly people can receive Ranopto without adjusting the dose.

Overdose:

If you think you, or a person you are caring for, have been given too much Ranopto, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose
If you forget to attend an appointment
Contact your healthcare professional or hospital as soon as possible to reschedule your appointment.

Before stopping Ranopto treatment
If you are considering stopping Ranopto treatment, please go to your next appointment and discuss this with your healthcare professional. Your healthcare professional will advise you and decide how long you should be treated with Ranopto.

If you have further questions on the use of this product, ask your healthcare professional.

What are possible side effects from using Ranopto?

As with all medicines, patients treated with Ranopto may experience side effects, although not everybody gets them. These are not all the possible side effects you may have when taking Ranopto. If you experience any side effects not listed here, tell your healthcare professional.

With administration of Ranopto, there may be some side effects, mostly in the eye and due to the injection procedure. Occasionally an infection in the internal portion of the eye, detachment or tear of the retina, or clouding of the lens may occur in the two weeks after Ranopto treatment. Other side effects include pain or redness and increased eye pressure. The symptoms you might experience are described in the "**Take special care with Ranopto"** Section of this leaflet. Please read this section. It tells you what to do if you have any of these symptoms.

Very common side effects (These may affect more than 1 in every 10 patients)
The most common side effects in the eye reported to be possibly caused by the medicinal product or by the injection procedure include:
- Bloodshot eye
- Eye pain
- Small particles or spots in your vision
- Increased pressure inside the eye
- Displacement of the jelly-like portion inside the eye (vitreous body)
- Swelling of the eye
- Blurred vision
- Eye irritation
- Clouding of the lens
- A feeling of having something in the eye
- Visual disturbance

- Swelling or infection of the eyelid margin
- Formation of fibrous tissue under the retina
- Redness of the eye
- Blurred or decreased sharpness of vision
- Dry eye
- Inflammation of the jelly-like portion inside the eye
- Temporary blindness
- Increased tear production
- Itching of the eye
- Detachment of a layer of the retina

The most common non-visual side effects reported to be possibly caused by the medicinal product or by the injection procedure include:
- Headache
- Elevated blood pressure
- Sore throat
- Pain in the joints

Common side effects (These may affect between 1 and 10 in every 100 patients)
Other common side effects in the eye reported to be possibly caused by the medicinal product or by the injection procedure include:
- Discomfort of the eye
- Clouding of a part of the lens
- Deposits in the back of the eye
- Infection of the surface of the eye
- Changes in the part of the retina responsible for central vision
- Bleeding in the back of the eye
- Degeneration of the retina
- Small scratches on the cornea (front part of the eye)
- Bleeding in the eye or at the site of injection
- Tear or detachment of the retina
- Redness of the eye
- Light sensitivity
- Swelling of the eyelid
- Eyelid pain
- Eye discharge
- Bleeding in the jelly-like portion inside the eye

Other common non-visual side effects reported to be possibly caused by the medicinal product or by the injection procedure include:
- Stroke
- Infection of the lower part of the airways
- Reduced number of red blood cells (you may experience tiredness, breathlessness, dizziness, pale skin)
- Feeling of tension or fullness in the nose, cheeks and behind the eyes sometimes with a throbbing ache
- Urinary tract (bladder) infection
- Flu
- Cough
- Nausea
- Back pain

- Inflammation of the joints
- Fatigue
- General feeling of being unwell
- Allergic reactions (rash, hives, itching, skin reddening)
- Changes in heart rhythm

Uncommon side effects (These may affect between 1 and 10 in every 1000 patients)
Uncommon side effects in the eye reported to be possibly caused by the medicinal product or by the injection procedure include:
- Irritation and edema of the eyelids
- Blindness
- Inflammatory deposits in the front part of the eye
- Reactions at the site of injection
- Abnormal sensation in the eye
- Blurred vision with light sensitivity
- Double vision
- Visual loss
- Distorted vision
- Serious allergic reaction

Other uncommon non-visual side effects reported to be possibly caused by the medicinal product or by the injection procedure include:
- Wheezing
- Increased secretion of the upper airways
- Inflammatory disease of the skin
- Heart attack
- Inflammation of the sinuses
- Increased skin sensitivity
- Feeling faint
- Low blood sugar
- Anxiety

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Pain or redness in the eye		√	
Detachment of the layer in the back of the eye		√	
Tear of the layer in the back of the eye		√	
Increased pressure in the eye		√	
Signs of stroke, such as weakness or paralysis of limbs or face, difficulty speaking or understanding. If you experience these signs, please go to the hospital emergency as immediate medical care is needed.		√	
Signs of non-ocular hemorrhage, such as black or tarry stool, vomit that looks like coffee grounds, weakness, headache of abrupt onset, nausea and vomiting, purplish bruises on the skin, etc		√	
UNCOMMON			
Infection in the eye		√	
Clouding of the lens		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Driving and using machines: After Ranopto treatment you may experience some short term vision blurring. If this happens, do not drive or use machines until this resolves.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Do not use Ranopto (ranibizumab injection) after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Do not use any pack that is damaged.
- Keep Ranopto (ranibizumab injection) out of reach and sight of children.
- Store vial in a refrigerator (2ºC – 8ºC). DO NOT FREEZE.
- Prior to use, the unopened vial may be stored at room temperatures up to 25°C for a maximum of 24 hours.
- Keep the vial in the outer carton in order to protect from light.

If you want more information about Ranopto:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the Canadian distributor (Teva Canada Innovation) website www.tevacanada.com or by calling 1-833-662-5644.

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