

## CONSUMER INFORMATION

**PrLUCENTIS\***  
ranibizumab injection

**This leaflet is part III of a three-part "Product Monograph" published when LUCENTIS\* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LUCENTIS\*. Contact your doctor, ophthalmologist or pharmacist if you have any questions about the drug.**

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor.

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

### ABOUT THIS MEDICATION

What the medication is used for:

LUCENTIS\* is given as an injection into the eye by your doctor under a local anaesthetic.

It is used to treat damage to the retina (the light-sensitive back part of the eye) when this damage is caused by abnormal blood vessels growing and leaking into the eye. This happens in diseases such as age-related macular degeneration (AMD). LUCENTIS\* has been shown to slow down the progression of vision loss and may improve vision.

What it does:

The active substance in LUCENTIS\* 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 attribute to the progression of AMD.

When it should not be used:

LUCENTIS\* must not be used

- if you are allergic to ranibizumab or any of the other ingredients of LUCENTIS\* listed below.
- if you have or suspect you have an infection in or around your eye.
- if you have pain or redness in your eye.

If this applies to you tell your doctor. You should not be given LUCENTIS\*.

If you have already experienced an allergic reaction tell your doctor before receiving LUCENTIS\*. If you think you may be allergic, ask your doctor for advice.

What the medicinal ingredient is:

The active substance in LUCENTIS\* is ranibizumab.

What the important nonmedicinal ingredients are:

The other inactive ingredients are:  $\alpha,\alpha$ -trehalose dihydrate; histidine hydrochloride, monohydrate; histidine; polysorbate 20; water for injection.

What dosage forms it comes in:

LUCENTIS\* is a solution for injection supplied in a clear, colourless glass vial. The vial contains 0.3 mL of a clear colourless to pale yellow solution.

LUCENTIS\* is supplied as a pack containing one glass vial of ranibizumab with chlorobutyl rubber stopper and one filter needle for withdrawal of the vial contents.

### WARNINGS AND PRECAUTIONS

**Take special care with LUCENTIS\***

- LUCENTIS\* 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 LUCENTIS\* treatment. It is important to identify and treat such a type of infection or retinal detachment as soon as possible. Please tell your doctor 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.

This is something you may not notice; however, after treatment with LUCENTIS\* your doctor may perform some additional tests to make sure there are no such complications

BEFORE you use LUCENTIS\* talk to your doctor or pharmacist if:

- you are taking or have recently taken any other medicines, including medicines bought without a prescription (over-the-counter) or natural health products.
- you are pregnant. There is no experience of using LUCENTIS\* in pregnant women. Discuss with your doctor if you are pregnant or planning to become pregnant.
- you are using or plan to use contraceptives during treatment with LUCENTIS\*
- you are breast-feeding. LUCENTIS\* is not recommended during breast-feeding because it is not known whether LUCENTIS\* passes into human milk. Ask your doctor or pharmacist for advice before LUCENTIS\* treatment.

The use of LUCENTIS\* in children and adolescents has not been studied and is therefore not recommended.

### PROPER USE OF THIS MEDICATION

All LUCENTIS\* injections will be administered by your doctor.

Follow carefully all instructions given to you by your doctor.

LUCENTIS\* is given as a single injection into your eye. The usual dose is 0.05 mL, equivalent to 0.5 mg. The injection is given once a month in the first 3 months. Your doctor will continue to monitor your vision and the frequency of dosing can be between 1 and 3 months. LUCENTIS\* given every 3 months was not as effective as when given once a month.

Before the injection, your doctor will use antibiotic eye drops or wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

Before and after each injection your doctor will ask you to use antibiotic eye drops or another type of

antibiotic treatment to prevent any possible eye infection.

Older people (age 65 years and over): LUCENTIS\* can be used for people 65 years of age and older without dosage adjustment.

### If you forget to attend an appointment

Contact your doctor or hospital as soon as possible to reschedule your appointment.

### Before stopping LUCENTIS\* treatment

If you are considering stopping LUCENTIS\* treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with LUCENTIS\*

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

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, LUCENTIS\* can cause side effects, although not everybody gets them. Please do not be alarmed by this list of side effects, you may not experience any of them.

With administration of LUCENTIS\*, 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 LUCENTIS\* treatment. Other side effects include pain or redness and increased eye pressure. The symptoms you might experience are described in the WARNINGS and PRECAUTIONS 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 10 or more in every 100 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
- bleeding in the back of the eye
- increased eye pressure
- displacement of the jelly-like portion inside the eye

- inflammation of the eye
- eye irritation
- clouding of the lens
- a feeling of having something in the eye
- visual disturbance
- inflammation 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

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

**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
- reactions at the site of the injection into the eye
- increased tear production
- itching of the eye
- infection of the surface of the eye
- changes in the part of the retina responsible for central vision
- detachment of a layer of the retina

Other common non-visual side effects reported to be possibly caused by the medicinal product or by the injection procedure include:

- infection of the lower part of the airways
- reduced number of red blood cells
- feeling of tension or fullness in the nose, cheeks and behind the eyes sometimes with a throbbing ache
- urinary track infection
- flu-like symptoms
- cough
- nausea
- back pain
- inflammation of the joints

**Uncommon side effects** (*These may affect less than 1 in every 100 patients*)

Uncommon side effects in the eye reported to be possibly caused by the medicinal product or by the injection procedure include:

- degeneration of the retina
- inflammation of the coloured part of the eye or the ciliary body or an internal part of the eye
- small marks on the surface of the eye
- changes in or thickening or thinning of the central part of the surface of the eye
- disorder in the back of the eye or the jelly-like portion inside the eye
- light sensitivity
- clouding of the central part of the lens
- signs of inflammation of the front part of the eye
- abrasion of the outer surface of the cornea
- a specific type of glaucoma
- bleeding in the jelly-like portion inside the eye
- infection of the eye globe
- tear or detachment of the retina
- bleeding in the eye
- irritation and edema of the eyelids
- blindness
- inflammatory deposits in the front part of the eye

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
- changes in heart rhythm
- inflammatory disease of the skin

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist	
		Only if severe	In all cases
Common	Pain or redness in the eye		√
	Increased pressure in the eye		√
Uncommon	Infection in the eye		√
	Detachment of the layer in the back of the eye		√
	Tear of the layer in the back of the eye		√
	Clouding of the lens		√

**This is not a complete list of side effects. If any of the side effects you experience gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.**

**Driving and using machines:** After LUCENTIS\* treatment you may experience some temporary vision blurring. If this happens, do not drive or use machines until this resolves.

**HOW TO STORE IT**

- Keep LUCENTIS\* out of reach and sight of children
- Store in a refrigerator (2°C – 8°C). DO NOT FREEZE.
- Keep the vial in the outer carton in order to protect from light.
- Do not use LUCENTIS\* after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.
- Do not use any pack that is damaged.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: [cadtmp@hc-sc.gc.ca](mailto:cadtmp@hc-sc.gc.ca)

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

***NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.***

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.novartis.ca>

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1-800-363-8883