**PART III: 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 affects you severely, 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 (pronounced "loo-SEN-tis") is given as an injection into the eye by a doctor under a local anesthetic.

In adults, LUCENTIS 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.

In preterm infants, LUCENTIS is used to treat retinopathy of prematurity (ROP).

If you are the parent or guardian of a baby who is being treated with LUCENTIS, the following also applies to your baby.

LUCENTIS has been shown to slow down the progression of vision loss, improve vision, as well as the ability to perform related activities (e.g. reading, driving, etc.).

For the following indication LUCENTIS has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- treat retinopathy of prematurity (ROP) with zone I [stage 1 with plus disease (1+), stage 2 with plus disease (2+), or stage 3 with or without plus disease (3 or 3+)], or zone II [stage 3 with plus disease (3+)] or aggressive posterior ROP (AP-ROP) disease.

For the following indications LUCENTIS has been approved without conditions. This means it has passed Health Canada's review and can be bought and sold in Canada.

- 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.

**What is a Notice of Compliance with Conditions (NOC/c)?**

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada

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 contribute to several eye diseases that may cause decreased vision.

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 think you may be allergic, ask your doctor for advice.
- If you have already experienced an allergic reaction tell your doctor before receiving LUCENTIS.
- If you have or suspect you have an infection in or around your eye.
- If you have pain or redness in your eye.

If any of these apply to you tell your doctor. You should not be given LUCENTIS.

Your baby must not receive LUCENTIS
- If your baby is allergic to ranibizumab or any of the other ingredients of this medicine listed below.
- If your baby has an infection in or around his/her eye.
- If your baby has pain or redness in his/her eye.

What the medicinal ingredient is:
The active substance in LUCENTIS is ranibizumab.

What the important nonmedicinal ingredients are:
The other inactive ingredients are: α,α-trehalose dihydrate; histidine hydrochloride monohydrate; histidine; polysorbate 20; water for injection.

What dosage forms it comes in:

*Vial (adults and preterm infants):*
LUCENTIS 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 to brown 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.

*Pre-filled syringe (adults only):*
LUCENTIS is a solution for injection supplied in a pre-filled syringe. The pre-filled syringe contains 0.165 mL of a sterile, clear, colourless to pale yellow to brown aqueous solution.

LUCENTIS is supplied as packs containing one sterile pre-filled syringe.

## WARNINGS AND PRECAUTIONS

**The warnings and precautions for adults also apply to preterm infants with ROP.**
**Potential systemic suppression of VEGF cannot be excluded following intravitreal administration of ranibizumab in premature infants with ROP.**
**The long-term safety profile in preterm infants with ROP has not been established.**

**Take special care with LUCENTIS**
- **Inform your doctor if you have already had a stroke or experienced short-lasting signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if LUCENTIS is the appropriate treatment for you**.
- 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. There have also been reports of a long-lasting increase in eye pressure. This is something you may not notice; therefore your doctor should check for this after each injection.
- Non-ocular hemorrhages have been reported after LUCENTIS treatment.
- Neurodevelopment impairment have been reported in preterm infants treated for ROP with anti-VEGF, including LUCENTIS.

If you notice any changes after you have been given LUCENTIS, **please inform your doctor immediately**.

Talk to your baby's doctor before your baby is given LUCENTIS.
- LUCENTIS is given as an injection into the eyes. Occasionally, an infection in the internal portion of the eye, pain or redness, detachment or tear of one of retina, or clouding of the lens may occur after LUCENTIS treatment. It is important to identify and treat such an infection or retinal detachment as soon as possible.
- In some patients the eye pressure may increase for a short period directly after the injection. Your baby's doctor may monitor this after each injection.

If you notice any changes after your baby has been given LUCENTIS, **please inform your baby's doctor immediately**

BEFORE LUCENTIS is given to your baby, tell your baby's doctor if your baby is receiving, has recently received or might receive any other medicines.

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 or planning to become pregnant. There is no clinical data on the use of LUCENTIS in pregnant women. Pregnancy should be avoided until at least three months after finishing LUCENTIS treatment. You should discuss with your doctor the potential risk of LUCENTIS during pregnancy.
- you are using or plan to use birth control 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 your doctor's instructions carefully.

LUCENTIS is given as a single injection into your eye. For adults the usual dose is 0.05 mL (which contains 0.5 mg of medicine). In preterm infants, the usual dose is 0.01 mL (which contains 0.1 mg of medicine). The time between two doses injected into the same eye should not be shorter than one month.

If you are treated for wet age-related macular degeneration, the injection is given once a month in the first 3 months. Afterwards, your doctor will continue to check 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.

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 doctor will monitor your vision monthly. If your vision remains the same while you are being given LUCENTIS treatment, your doctor may decide to stop the treatment with LUCENTIS. Your doctor will continue to monitor your vision monthly and will decide if treatment with LUCENTIS should be resumed or not. Your doctor may decide that you also need to be treated with laser for these conditions, if so, laser treatment can be administered together with LUCENTIS.

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

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

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

If your baby is treated for retinopathy of the prematurity (ROP), LUCENTIS is administered as a single injection into your baby's eyes by the eye doctor under a local anaesthetic. If ROP is present in both eyes, a second injection of LUCENTIS can be given to your baby on the same day. The usual dose of an injection is 0.01 ml (which contains 0.1 mg of active substance). The interval between two doses injected into the same eyes should be at least four weeks. All injections will be administered by the eye doctor.

Before the injection, your baby's doctor will wash your baby's eyes carefully to prevent infection. The doctor will also give your baby a local anaesthetic to reduce or prevent any pain it might have with the injection.

The doctor will monitor the condition of your baby's eye and, depending on how your baby responds to the treatment, will decide if and when your baby will need to receive further injection of LUCENTIS.

Older people (65 years or above): Elderly people can receive LUCENTIS without adjusting the dose.

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

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

**Overdosage:**

For management of a suspected drug overdose, contact your regional Poison Control Centre.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with LUCENTIS may experience side effects, although not everybody gets 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.

The most common side effects in babies born prematurely are described below:
Visual side effects include: Bleeding in the back of the eye (retinal bleeding), bloodshot eye (conjunctival bleeding), bleeding into the thick fluid that fills the center of the eye (vitreous hemorrhage) and inflammation or infection of the transparent membrane (conjunctivitis).

Non-visual side effects include fever, nasal congestion, runny nose and cough (upper respiratory tract infection), low red blood cell counts (with symptoms such as tiredness, breathlessness, pale skin), urinary tract infection, allergic reactions like rash and skin reddening, diarrhea and slow heart rate (bradycardia).

Additional side effects that have been observed with LUCENTIS in adults are listed below. These side effects may also occur in babies born prematurely.

**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
- seeing spots or cobwebs (floaters)
- 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
- vision change
- swelling or infection of the rim of the eye
- 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, 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 | | √ |
| | 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. | | √ |
| | 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.<br>If you experience these signs, please go to the hospital emergency as immediate medical care is needed. | | √ |
| Uncom-mon | Infection in 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 short term vision blurring. If this happens, do not drive or use machines until this resolves.

## HOW TO STORE IT

- Do not use LUCENTIS 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 LUCENTIS out of reach and sight of children.

*Vial:*
- Store in a refrigerator (2ºC – 8ºC). DO NOT FREEZE.
- Prior to use, the unopened vial may be kept at room temperature (25°C) for up to 24 hours.
- Keep the vial in the outer carton in order to protect from light.

*Pre-filled syringe:*
- Store in a refrigerator (2ºC – 8ºC). DO NOT FREEZE.
- Prior to usage, the unopened tray may be kept at room temperature (25°C) for up to 24 hours.
- Keep the pre-filled syringe in its sealed tray in the carton in order to protect from light.

## REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

Fax toll-free to 1-866-678-6789, or

Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

## MORE INFORMATION

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

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