Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]LUXTURNA®[Lucks-turn-a]

voretigene neparvovec

This Patient Medication Information is written for the person who will be taking **LUXTURNA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LUXTURNA**, talk to a healthcare professional.

What LUXTURNA is used for:

LUXTURNA is a gene therapy product used for the treatment of adults and children with vision loss due to inherited retinal dystrophy caused by mutations in the *RPE65* gene. These mutations prevent the body from producing a protein needed for vision which can lead to loss of sight and eventual blindness.

LUXTURNA will be given to you only if genetic testing shows that your vision loss is caused by confirmed biallelic mutations in the *RPE65* gene.

How LUXTURNA works:

The active substance in LUXTURNA, voretigene neparvovec, is a modified virus that contains a working copy of the *RPE65* gene. After injection it delivers this gene into the cells of the retina, the layer at the back of the eye that detects light. This enables the retina to produce the proteins needed for vision. The virus used to deliver the gene does not cause disease in humans.

If you have any questions about LUXTURNA, how it works or why this medicine has been prescribed for you, ask your healthcare professional.

The ingredients in LUXTURNA are:

Medicinal ingredient: Voretigene neparvovec

Non-medicinal ingredients: *Concentrate and Diluent*: Disodium hydrogen phosphate dihydrate (for pH adjustment), sodium chloride, sodium dihydrogen phosphate monohydrate (for pH adjustment), poloxamer 188, water for injections.

LUXTURNA contains no preservatives.

LUXTURNA comes in the following dosage form:

LUXTURNA concentrate and the diluent are both clear, colorless liquids. LUXTURNA vial contains 5×10^{12} vector genomes (vg) per mL of voretigene neparvovec.

Do not use LUXTURNA if:

- you are allergic (hypersensitive) to voretigene neparvovec, any of the other ingredients of LUXTURNA or component of the container.

- you have an eye infection.
- you have an eye inflammation.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive LUXTURNA. Talk about any health conditions or problems you may have, including if you:

- think you may be allergic to this drug or its ingredients.
- have signs of an eye infection or eye inflammation, for example if you have eye redness, sensitivity to light, eye swelling or eye pain.
- have an active infection of any sort. Your doctor may delay your treatment until your infection is gone because this medicine may make it more difficult for you to fight an infection. See also "How to receive LUXTURNA".
- are pregnant or plan to become pregnant.
- are breastfeeding.

Other warnings you should know about:

LUXTURNA will be injected into your eye in an operating room by surgeons experienced in performing eye surgery.

After receiving LUXTURNA:

- Get immediate care from your healthcare professional if your eye or eyes become red, painful, sensitive to light, you see flashes or floaters in your vision, or if you notice any worsening or blurred vision.
- Permanent decline in visual acuity may occur following subretinal injection of LUXTURNA. Contact your healthcare professional or pharmacist if you experience any changes in vision.
- You should rest laying on your back as much as possible for 24 hours after discharge.
- You should avoid air travel or travel to high elevations until advised by your healthcare professional. During treatment with this medicine, the surgeon inserts an air bubble in the eye, which is slowly absorbed by your body. Until the bubble is fully absorbed, air travel or travel to high elevations may make the bubble expand and lead to eye damage, including vision loss. Please talk to your healthcare professional before traveling.
- You should avoid swimming because of an increased risk of infection in the eye. Please talk to your healthcare professional before you resume swimming.
- Some people develop cataracts. A cataract is clouding of the natural lens inside the eye that can make it harder to see clearly. The development or worsening of cataracts is a known complication of the eye surgery that will be required before you receive LUXTURNA. There is an additional risk of cataract if the lens inside the eye is damaged by the needle used to inject the medicine into the back of the eye.
- You and your caregiver, especially if pregnant, breastfeeding or with a suppressed immune system, should wear gloves during dressing changes and when disposing of the dressings and other waste material. Follow these precautions for 14 days after the treatment.
- You and your caregiver should place any used dressings and waste material with tears and nasal

secretions in sealed bags before disposing of them. You and your caregiver should follow these precautions for 14 days.

- You will not be able to donate blood, organs, tissues and cells for transplantation. This is because LUXTURNA is a gene therapy product.

Children (below 4 years of age)

LUXTURNA has not been studied in children under four years of age.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you might be pregnant, or are planning to have a baby, ask your healthcare professional or nurse for advice before being treated with LUXTURNA.

The effects of this medicine on pregnancy and your unborn child are not known. As a precaution, you should not receive LUXTURNA while you are pregnant.

It is not known whether LUXTURNA passes into breast milk. Ask your healthcare professional whether you should stop breastfeeding after receiving LUXTURNA.

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 LUXTURNA:

No relevant interactions are known.

How to receive LUXTURNA:

LUXTURNA will be injected into your eye in an operating room by surgeons experienced in performing eye surgery.

LUXTURNA is given under anesthesia. Your healthcare professional will talk to you about the anesthesia and how it will be given to you.

Your healthcare professional will carry out eye surgery to remove the clear gel inside the eye, and then inject LUXTURNA directly under your retina, the thin light-sensing layer at the back of that eye. This may be repeated in your other eye at least 6 days afterwards. You will need to stay for post-operative observation for a few hours after each procedure to monitor your recovery and watch for any side effects from the surgery or the anesthesia.

Before LUXTURNA treatment is started, your healthcare professional may prescribe a medicine that will suppress your immune system (the body's natural defenses) so that it will not try to fight the LUXTURNA when it is given. It is important that you take this medicine according to the instructions given. Do not stop taking the medicine without first talking to your healthcare professional.

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

Usual dose:

You will receive a single dose of 1.5×10^{11} vg of LUXTURNA in each eye. Each dose will be injected directly under your retina in a total volume of 0.3 mL. LUXTURNA is given to each eye on separate days, at least 6 days apart.

Overdose:

If you think you, or a person you are caring for, have been given too much LUXTURNA, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

Possible side effects from using LUXTURNA:

As with all medicines, patients treated with LUXTURNA may experience side effects, although not everybody gets them. The side effects associated with the administration of LUXTURNA are either due to the medicine itself, the injection procedure, or the use of corticosteroids and mostly affect the eye.

These are not all the possible side effects you may have when receiving LUXTURNA. If you experience any side effects not listed here, contact your healthcare professional.

If these side effects become severe, please tell your healthcare professional.

Very common: *may affect more than 1 in 10 people*

- Redness of the eye
- Cataract (clouding of the lens)
- Increased pressure in the eye

Common: *may affect up to 1 in every 10 people*

- Deposits under the retina
- Break in the retina (retinal tear)
- Abnormalities in the back of the eye
- Thinning of the surface of the eye (dellen)
- Eye pain
- Eye swelling
- Eye irritation
- Eye inflammation
- Foreign body sensation in the eye
- Detachment of the retina

Not known: *frequency cannot be estimated from the available data*

- Thinning of the retina (chorioretinal atrophy)

Damage to the tissues of the eye may be accompanied by bleeding and swelling and an increased risk of infection. There is reduced vision in the days after surgery that usually improves; tell your healthcare professional if vision does not return.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
COMMON Inflammation, infection or allergic reaction of the eye:			√

• a sudden decrease or change in vision, • an increase in pain, discomfort or redness in your eye.			

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

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 (canada.ca/drug-device-reporting), for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

LUXTURNA will be stored by the healthcare professionals at your healthcare facility. You will not store LUXTURNA yourself.

If you want more information about LUXTURNA:

- 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 Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website http://www.novartis.ca or by calling 1-800-363-8883.

This leaflet was prepared by:

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