▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LUXTURNA®

concentrate and solvent for solution for injection

voretigene neparvovec

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you receive Luxturna.

This leaflet answers some common questions about Luxturna. It does not contain all the available information. It does not take the place of talking to your doctor.

You can also download the most up to date leaflet from www.novartis.com.au or from www.ebs.tga.gov.au/

Your doctor will give you a Patient Alert Card. Read it carefully and follow the instructions on it.

Also show the Patient Alert Card to your (or your child's) doctor or nurse when you see them if you (or child) go to hospital or a medical centre.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Luxturna against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with you as you may need to read it again.

What Luxturna is used for

Luxturna is used to treat patients with an inherited change (mutations) in the gene RPE65.

These mutations prevent the body from producing a protein needed for vision and so lead to loss of sight and eventually blindness.

Your doctor will assess if you have sufficient retinal cells to benefit from Luxturna treatment.

The active substance in Luxturna is voretigene neparvovec which is a modified virus containing a copy of the RPE65 gene. After it is injected 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 that is used to deliver the gene does not cause disease in humans.

Ask your doctor if you have any questions about why Luxturna has been prescribed for you.

Use in Children

Luxturna is not recommended for use in children under 4 years of age.

The safety and effectiveness of Luxturna has not been established in this age group.

Before you are given Luxturna

When you must not be given it

Do not use if:

- you have an eye infection or your eyes are inflamed.

Symptoms include redness of the eye, sensitivity to light, eye swelling or eye pain.

Tell your doctor if you have any other infection.

Your doctor may delay treatment until your infection is gone as Luxturna treatment may make it more difficult for you to fight infection.

- you are allergic to voretigene neparvovec or the ingredients in Luxturna listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Tell your doctor if you have allergies to any other medicines or any substances such as foods, preservatives or dyes.

If you are not sure whether you should be given Luxturna talk to your doctor.

Before you start to use it

Tell your doctor if you are pregnant or plan to become pregnant.

The effects of Luxturna in pregnancy have not been studied.

Tell your doctor if you are breastfeeding or plan to breastfeed.

The effects of Luxturna whilst breastfeeding have not been studied.

Tell your doctor if you have any other medical conditions.

If you have not told your doctor about any of the above, tell them before you receive Luxturna.

Using or taking other medicines

Tell your doctor, pharmacist or nurse if you are taking or using any other medicines, including medicines that you buy at a pharmacy, supermarket or health food shop.

Your doctor will be able to tell you if these will affect the way Luxturna works.

How you will be given Luxturna

Before you receive Luxturna

Your doctor will prescribe a medicine that will suppress your immune system (the body's natural defenses) so that your body will not fight the effects of Luxturna when it is given.

It is important that you take this medicine as instructed by your doctor. You should not stop taking this medicine without talking to your doctor.

How you will be given Luxturna

You will be given Luxturna in an operating room. It will be injected into your eye by a surgeon experienced in performing eye surgery.

Luxturna is given under anaesthesia. Your doctor will talk to you about the anaesthetic and how it will be given to you.

Your doctor will carry out eye surgery to remove the gel inside the eye, and then inject Luxturna directly into the retina, the thin light-sensing layer at the back of the eye. This surgery will be repeated on 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 either the surgery or anaesthesia.

How long to use it

You will only receive Luxturna once in each eye.

If you receive too much (overdose)

It is unlikely that you will be given too much Luxturna as it will be given to you by a doctor. If this occurs, your doctor will treat the symptoms as needed.

After you receive Luxturna

Things to be careful of

Be careful driving or operating machinery until your vision has recovered after receiving Luxturna.

Things to be aware of

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 eye surgery. 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.

See your doctor immediately if your eye or eyes become red, painful, sensitive to light, you see flashes or floaters in your vision, of if you notice any worsening or blurred vision.

Some of your medicine may be present in your tears.

You and your caregiver should wear gloves during dressing changes, especially if you are pregnant, breastfeeding or have a suppressed immune system. You and your caregiver should continue to wear gloves when disposing of the dressings and other waste material.

Patients and caregivers should follow the advice given to them by their doctor or pharmacist for the appropriate method of disposing of waste materials. If no advice is given then the sealed bags may be put in normal household waste.

Follow these precautions for 14 days after the treatment.

You should avoid air travel or travel to high elevations until advised by your doctor. During treatment with this medicine, the doctor inserts an air bubble in the eye, which 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 doctor before traveling.

You should avoid swimming because of an increased risk of infection in the eye. Please talk to your doctor before you resume swimming after receiving treatment with Luxturna.

You will not be able to donate blood, organs, tissues and cells for transplantation after you have been treated with Luxturna. This is because Luxturna is a gene therapy product.

Side effects

Tell your doctor as soon as possible if you do not feel well after Luxturna treatment.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need to seek medical treatment if you get some of the side effects.

These may be due to Luxturna or the injection procedure, or the use of the anti-inflammatories that will be given to you before your surgery.

Do not be alarmed by the following list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following effects in the eye(s) and the eye area and they worry you.

Very common side effects (may affect more than 1 in 10 people) include:

- Redness of the eye
- Clouding of the lens (cataract)
- Increased pressure in the eye.

Common side effects (may affect up to 1 in every 10 people) include:

- 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.

The frequency of some side effects 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 doctor if your vision does not return.

See your doctor immediately 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.

Tell your doctor or pharmacist if:

- you experience a permanent decline in your vision.

This may occur after injection of Luxturna into the retina.

- you experience any changes in vision.

See your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following symptoms which may be due to either inflammation, infection or an allergic reaction in the eye:

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

Tell your doctor immediately if you experience any serious side effects.

Tell your doctor, pharmacist or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Luxturna

Storage

Luxturna will be stored by a healthcare professional at your healthcare facility.

The concentrate and solvent must be stored and transported frozen at less than or equal to minus 65°C. Once thawed, the medicine should not be re-frozen and should be left at room temperature (below 25°C).

Do not use this medicine after the expiry date which is stated on the label and carton after EXP.

Product description

What it looks like

Luxturna is a clear, colourless concentrate for solution for subretinal injection. It is supplied in a clear plastic vial.

The solvent is a clear, colourless liquid supplied in a clear plastic vial.

Each foil pouch includes a carton containing 1 vial of the concentrate and 2 vials of solvent.

Ingredients

Luxturna contains the active substance voretigene neparavovec. Each mL contains 5×10^{12} vector genomes (gv). The concentrate (0.5 mL extractable volume in a single-dose 2 mL vial) requires a 1:10 dilution prior to administration.

Each dose of diluted solution contains 1.5×10^{11} vector genomes of voretigene neparavovec in a deliverable volume of 0.3 mL.

Luxturna also contains the inactive ingredients:

- sodium chloride
- monobasic sodium phosphate
- dibasic sodium phosphate
- poloxalene
- water for injections.

Sponsor

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

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Telephone no. 1800 671 203.

Website:

www.novartis.com.au

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