Luxturna®

Concentrate and solvent for solution for injection

Voretigene neparvovec

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I given Luxturna?

Luxturna contains the active substance Voretigene neparvovec. Luxturna is used to treat certain genetic diseases that damage the retina (the layer at the back of the eye that detects light) caused by RPE65 mutations.
For more information, see Section 1. Why am I given Luxturna? in the full CMI.

2. What should I know before Luxturna is given?

Do not use if you have ever had an allergic reaction to Luxturna or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before Luxturna is given? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Luxturna and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will you be given Luxturna?

- Your doctor will prescribe you certain medicines prior to treatment with Luxturna.
- Follow the instructions given by your doctor carefully.

More instructions can be found in Section 4. How will you be given Luxturna? in the full CMI.

5. What should I know when Luxturna is given?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you have used Luxturna. • Avoid air travel or travel to high elevations until your doctor tells you to. • Call your doctor straight away if you notice any problems with your vision.
Things you should not do	• Do not donate blood, organs, tissues and cells for transplantation after treatment with Luxturna. • Avoid swimming because of an increased risk of infection in the eye.
Driving or using machines	• Luxturna may cause temporary vision problems. • Do not drive or use heavy machines until your vision has recovered sufficiently.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Luxturna will be stored by a healthcare professional at your healthcare facility.

For more information, see Section 5. What should I know when Luxturna is given? in the full CMI.

6. Are there any side effects?

Common side effects include eye pain, eye irritation, vision problems, increased sensitivity to light, feeling that something is in your eye(s), redness of the eye(s), eye swelling, headache, blurred vision.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. 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

Active ingredient: *VORETIGENE NEPARVOVEC*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Luxturna. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Luxturna.**

Where to find information in this leaflet:

1. Why am I given Luxturna?

Luxturna contains the active substance Voretigene neparvovec. It is a modified virus containing a copy of the RPE65 gene.

Luxturna is used to treat certain genetic diseases that damage the retina (the layer at the back of the eye that detects light) caused by RPE65 mutations. These mutations prevent the body's ability to produce a protein required for vision, that results in vision loss and eventually blindness.

Your doctor will assess if you have enough retinal cells for Luxturna to work properly.

Voretigene neparvovec is a modified virus that carries a copy of the RPE65 gene. Once injected into the eye, it delivers this gene to retinal cells. This enables the retina to produce essential proteins needed for vision. The virus that is used to deliver the gene does not cause disease in humans.

2. What should I know before Luxturna is given?

Warnings

Do not use Luxturna:

- If you are allergic to Voretigene neparvovec, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- If you suffer from any eye infections or eye swelling. Symptoms include redness of the eye, eye swelling, eye pain, sensitivity to light.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- suffer from increased eye pressure.
- have diseases of cornea with symptoms such as eye pain, feeling that something is in your eye(s), sensitivity to light.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Avoid the use of Luxturna during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise you regarding the possible risks and benefits of using Luxturna during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Luxturna.

4. How will you be given Luxturna?

How much to use

Before you receive Luxturna:

- Your doctor will prescribe you certain medicines prior to treatment with Luxturna.
- Follow the instructions given by your doctor carefully.

How you will be given Luxturna:

- You will be given Luxturna in an operating room by a surgeon experienced in performing eye surgery. It will be injected into your eye.
- Luxturna is given under anaesthesia. Your doctor will talk to you about the process of anaesthesia.

- Your doctor will carry out eye surgery, 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.

If you use too much Luxturna

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.

5. What should I know when Luxturna is given?

Things you should do

- Avoid air travel or travel to high elevations until your doctor tells you to.
- Some of the 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 any problems with your immune system.
- You and your caregiver should continue to wear gloves when disposing of the dressings and other waste material.

Call your doctor straight away if you:

- develop any signs of an allergic reaction.
- develop any symptoms of an eye infection or swelling, symptoms such as redness of the eye, eye swelling, eye pain, sensitivity to light.
- you see flashes or floaters, or if you notice any worsening or blurred vision.
- have any signs or symptoms such as flashes of light in your vision, reduced vision or blurred or distorted vision e.g. seeing straight lines as wavy.

Remind any doctor, dentist, pharmacist or specialist you visit that you have used Luxturna.

Things you should not do

- Do not donate blood, organs, tissues and cells for transplantation after treatment with Luxturna. This is because Luxturna is a gene therapy product.
- Avoid swimming because of an increased risk of infection in the eye. You may resume swimming after a minimum of one to two weeks, on the advice of your doctor.
- Do not use Luxturna in children under 4 years of age.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Luxturna affects you and follow the advice given by your doctor.

Luxturna may cause temporary vision problems.

Do not drive or use heavy machines until your vision has recovered sufficiently.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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).

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye Problems: • Temporary appearance of dot-like or yellowish material that builds up beneath the retina (the layer at the back of the eye that detects light) • Headache, blurred vision, eye pain • Eye irritation • Eye pain • Redness of the eye(s) • Eye problems • Eye swelling • Feeling that something is in your eye(s)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Eye problems: • Gradual decline in vision, difficulty with night vision, vision distortions e.g. seeing straight lines as wavy. • Flashes of light in your vision, floaters, loss of side vision, reduced vision • Involuntary eye movements • Presence of a white or yellow discharge on or inside the eyelid. • Increased sensitivity to light, blurry or distorted vision e.g.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
seeing straight lines as wavy. decreased vision • Blurry or foggy vision, sudden floaters or flashes of light, sudden vision loss. • Sensation of eye flashes • Severe eye pain, loss of vision, extreme sensitivity to bright light. • Increased difficulty in seeing in low light, blurry vision • Blurred vision, difficulties distinguishing colour • Visible clear, small bump on the eye, discomfort • Clouded, blurred, or dim vision, difficulty seeing at night, sensitivity to light. • Eye discomfort or feeling that something is in your eye(s), blurry vision • Blurry, wavy or distorted vision • Flashes of light in your vision, blurred vision	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Luxturna contains

Active ingredient (main ingredient)	Voretigene neparvovec Luxturna concentrate for subretinal injection contains 5 x 1012 vector genomes (vg) per mL. The concentrate (0.5 mL extractable volume in a single-dose 2 mL vial) requires a 1:10 dilution prior to administration. After dilution, each dose contains 1.5 x 1011 vg in a deliverable volume of 0.3 mL.
Other ingredients (inactive ingredients)	Concentrate: Sodium chloride, monobasic sodium phosphate (for pH adjustment), dibasic sodium phosphate (for pH adjustment), poloxalene, water for injections. Diluent: Sodium chloride, monobasic sodium phosphate (for pH adjustment), dibasic sodium phosphate (for pH adjustment), poloxalene, water for injections.
Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

What Luxturna looks like

Luxturna is a clear, colourless preservative-free liquid.

It is supplied in 0.5 mL extractable volume of concentrate in 2 mL cyclic olefin polymer vial with a chlorobutyl rubber stopper sealed in place with an aluminium flip-off seal.

1.7 mL extractable volume of solvent in a 2 mL cyclic olefin polymer vial with a chlorobutyl rubber stopper sealed in place with an aluminium flip-off seal.

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

Australian registration number: AUST R: 318929.

Who distributes Luxturna

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

54 Waterloo Road

Macquarie Park NSW 2113

Telephone no. 1800 671 203.

Website:

www.novartis.com.au

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