Package leaflet:
Information for the patient

Luxturna (voretigene neparvovec) SFDA approved RMP Educational Materials V 1.5 Sep 2025

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

NOVARTIS

Package leaflet:
Information for the patient

Luxturna *5×10^{12} vector genomes/mL concentrate and solvent for solution for injection voretigene neparvovec*

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- For Full prescribing information, please refer to www.ema.europa.eu/en
  This link will contain the most updated product information approved by the reference country

1.

2.

What is in this leaflet:

1. What Luxturna is and what it is used for

Luxturna is a gene therapy product that contains the active substance voretigene neparvovec.

Luxturna is 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 and so lead to loss of sight and eventual blindness.

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.

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

2. What you need to know before you are given Luxturna

You will not be given Luxturna

if you are allergic to voretigene neparvovec or any of the other ingredients of this medicine (listed in section 6)
if you have an eye infection
if you have eye inflammation

If **any of the above applies to you, or if you are unsure of any of the above, please talk to** your doctor before you receive Luxturna.

Warnings and precautions

Before receiving treatment with Luxturna:

- Tell your doctor if you have signs of an eye infection or eye inflammation, for example if you have eye redness, sensitivity to light, eye swelling or eye pain.
- Tell your doctor if you 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 section 3.

After receiving Luxturna:

- Get immediate care from your doctor 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.

- You should avoid air travel or other 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 slowly absorbed by your body. Until the bubble is fully absorbed, air travel or other travel to high elevations may make the bubble expand and lead to eye damage, including vision loss. Please talk to your doctor before travelling.

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

- You should avoid strenuous physical activity because of an increased risk of injury to the eye. Please talk to your doctor before beginning to engage in strenuous physical activity after receiving Luxturna.

- You may have temporary visual disturbances, such as light sensitivity, and blurred vision. Tell your doctor about any visual disturbances that you experience. Your doctor may be able to help reduce any discomfort caused by these temporary disturbances.

- The active substance in Luxturna may temporarily be excreted through your tears. 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 should follow these precautions for 14 days.

- You might not be able to donate blood, organs, tissues and cells for transplantation after you have been treated with Luxturna.

Children and adolescents

Luxturna has not been studied in children below 4 years of age. Data are limited.

Other medicines and Luxturna

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor or nurse for advice before being treated with Luxturna.

The effects of this medicine on pregnancy and the unborn child are not known. As a precaution, you should not receive Luxturna while you are pregnant.
Luxturna has not been studied in breast-feeding women. It is not known whether it passes into breast milk. Tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or to not receive Luxturna, taking into account the benefit of breastfeeding for your baby and the benefit of Luxturna for you.

Driving and using machines

You may have temporary visual disturbances after receiving Luxturna. Do not drive or use heavy machines until your vision has recovered. Talk to your doctor before resuming these activities.

Luxturna contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Luxturna is given to you

Luxturna will be given to you in an operating room by surgeons experienced in performing eye surgery.

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

Your doctor 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 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 the surgery or the anaesthesia.

Before Luxturna treatment is started your doctor may ask you to take a medicine that will suppress your immune system (the body's natural defences) 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 doctor.

If you are given more Luxturna than you should be

As this medicine is given to you by a doctor, it is unlikely that you will be given too much. If it does occur, your doctor will treat the symptoms as necessary. Tell your doctor or nurse if you have any visual problems.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with Luxturna:

Common (may affect up to 1 in 10 people)

- Deposits under the retina

Not known (frequency cannot be estimated from the available data)

- Atrophy of the (chorio)retina

The following side effects may happen with the injection procedure:

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 10 people)

- Break in the retina
- Eye pain
- Eye swelling
- Detachment of the retina
- Bleeding in the back of the eye
- Pain or increased discomfort in the eye
- Blurring of central vision due to hole in the centre of the retina
- Thinning of the surface of the eye (dellen)
- Eye irritation
- Eye inflammation
- Foreign body sensation in the eye
- Eye discomfort
- Abnormalities in the back of the eye
- Nausea (feeling sick), vomiting, abdominal (belly) pain, lip pain
- Change of the electrical activity of the heart
- Headache, dizziness
- Rash, facial swelling
- Anxiety
- Problems associated with the placement of a breathing tube in the windpipe
- Breakdown of the surgical wound

Not known (frequency cannot be estimated from the available data)

- Clouding in the gel-like substance inside the eye (vitreous opacities)
- Atrophy of the (chorio) retina

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 vision does not return.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via *www.report.novartis.com*
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Luxturna is stored

Luxturna will be stored by the healthcare professionals at your healthcare facility.
Concentrate and solvent must be stored and transported frozen at ≤-65 ºC. 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.

6. Contents of the pack and other information

What Luxturna contains

- The active substance is voretigene neparvovec. Each mL of concentrate contains 1012 × 5 vector genomes (vg). 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 1011 × 1.5 vector genomes of voretigene neparvovec in a deliverable volume of 0.3 mL.

- The other ingredients of the concentrate are sodium chloride (see "Luxturna contains sodium" in section 2 of this leaflet), sodium dihydrogen phosphate monohydrate (for pH adjustment), disodium hydrogen phosphate dihydrate (for pH adjustment), poloxamer 188 and water for injections.

- The solvent contains sodium chloride (see end of section 2), sodium dihydrogen phosphate monohydrate (for pH adjustment), disodium hydrogen phosphate dihydrate (for pH adjustment), poloxamer 188 and water for injections.

  This medicine contains genetically modified organisms.

What Luxturna looks like and contents of the pack

- Luxturna is a clear, colourless concentrate for solution for subretinal injection, 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 0.5 mL concentrate and 2 vials of solvent (each containing 1.7 mL).

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Keep medicaments out of reach of children

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in thisleaflet. You can also report side effects directly via www.report.novartis.com. By reporting side effects, you can help provide more information on the safety of this medicine.

You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia -.
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: https://report.novartis.com/

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Fax: +966112057662
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Other sources of information

This leaflet is available as an audio file and in a large print from the web site:
www.https://voretigeneneparvovec.support

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Patient Safety Department Novartis Pharma AG - Saudi Arabia - Toll Free Number: 8001240078 Phone: +966112658100 Fax: +966112658107
Email: adverse.events@novartis.com Or by online: https://report.novartis.com/

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Saudi Food and Drug Authority National Pharmacovigilance Center Toll free phone: 8002490000 Fax:+966112057662 E-mail: npc.drug@sfda.gov.saOr by online: https://ade.sfda.gov.sa

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LUXTURNA®
voretigene neparvovec
for subretinal injection