

**PATIENT INFORMATION**  
**ENCELTO (En-SEL-toh)**  
**A surgical implant for use in the eye**

**What is ENCELTO?**

ENCELTO is an encapsulated cell-based gene therapy. It is a small capsule, about the size of a grain of rice, that is placed inside the eye to release a protein called recombinant human ciliary neurotrophic factor (rhCNTF) that can directly reach the retina, the light sensitive part of the eye. The capsule contains living cells that have been genetically modified to continuously produce and release CNTF. This protein helps protect certain cells in your retina, supporting their health and reducing the loss of light-sensing cells known as photoreceptors.

ENCELTO is used to treat adults with idiopathic macular telangiectasia type 2 (MacTel); a retinal disease that causes progressive vision loss. Your ophthalmologist will assess your vision and review your medical history to determine if ENCELTO is the right treatment for you.

**Who should not receive an ENCELTO surgical implant?**

ENCELTO has not been tested in pediatric patients or pregnant women.

The outpatient surgical procedure should not be performed if you are currently experiencing an active or suspected eye infection.

You should not receive ENCELTO if you have a known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

**Before receiving ENCELTO, tell your ophthalmologist about all your medical conditions, including:**

- Are pregnant or plan to become pregnant. Although studies have shown that rhCNTF does not enter the bloodstream, its effects on an unborn baby have not been fully studied.
- Are breastfeeding or plan to breastfeed. It is not known if rhCNTF passes into your breast milk.
- Any current infections
- Are currently taking or have recently taken medicines that lower the chance of blood clots forming in the body such as warfarin, low or regular doses of aspirin, or nonsteroidal anti-inflammatory drugs (NSAID)

**How is ENCELTO administered?**

ENCELTO is inserted into the eye as an outpatient surgical procedure performed by an ophthalmologist experienced in retinal surgery. If removal of ENCELTO is necessary, the removal surgery must also be done by an ophthalmologist experienced in vitreoretinal surgery in an operating room as an outpatient surgery.

## What should I avoid after placement of ENCELTO?

Immediately post-operative:

- Avoid heavy lifting (over 20 pounds) for one week.
- Keep water out of the eye (e.g., close your eye while showering) for one week.
- Protect your eyes by wearing glasses or protective eyewear during the day and using an eye shield at night for one week.
- Do not drive or use machinery until the eye shield has been removed and your ophthalmologist informs you that your vision has recovered to an acceptable level.

Post operative care:

- Use a topical antibiotic solution at a frequency of 1 drop four times a day for 7 days.
- Use a steroid drop taper of prednisolone acetate 1% (or equivalent) starting the day after surgery with the following taper:
  - 1 drop four times a day for the first 7 days;
  - 1 drop three times a day for the next 7 days;
  - 1 drop two times a day for the next 7 days;
  - 1 drop once a day for the last 7 days.

### **Magnetic Resonance (MR) Conditional Information**



**IMPORTANT: ENCELTO is MR conditional.** You will receive an implant card, which should be shown to your imaging technician if you need Magnetic Resonance Imaging (MRI) at any time while the ENCELTO implant is in your eye. The card will include details about the ENCELTO implant, the date of insertion, and on the back, instructions for the imaging technician to access important MRI safety information.

Call your ophthalmologist for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.

## **What are the possible side effects of ENCELTO?**

Please follow all post-operative instructions given by your ophthalmologist and ensure you attend all follow-up visits as recommended.

### **Potential side effects**

Please be advised that ENCELTO and the surgical insertion has related risks such as, but not limited to, endophthalmitis (eye infection), retinal tear and detachment (retina tears and potentially separates from the eye wall resulting in vision loss), vitreous hemorrhage (bleeding within the central cavity of the eye), implant extrusion (the ENCELTO begins to work its way out of the eye), suture related issues (such as suture related eye irritation or exposure of sutures), temporary or permanent loss of vision, accelerated cataract formation (clouding of the lens of the eye), and delayed dark adaptation (the ability of the eye to adjust from bright lighting conditions to dark lighting conditions).

If delayed dark adaptation occurs, it is unknown for how long these symptoms will be experienced. Take the following safety precautions.

- Driving: delayed dark adaptation may impair one's ability to see objects, pedestrians, or road signs when moving rapidly from a brightly lit environment to a dimly lit environment (for example, entering a tunnel during the daytime).
- Navigating in the Dark: Take caution when moving from bright to dark areas, such as entering a dark room or stepping outside at dusk. Consider using flashlights, nightlights, or motion-activated lighting at home.
- Consider wearing sunglasses or tinted lenses in bright environments to reduce the impact of transitioning from light to dark

It is common to experience the following symptoms following ENCELTO surgery:

- Sensation of something in the eye (i.e., foreign body sensation)
- Eye redness
- Eye irritation
- Eye dryness
- Eye discharge
- Mild to moderate eye pain or discomfort
- Floaters (small spots or shapes that appear in your vision)
- Headache

### **When to Seek Ophthalmologist Advice**

You are to seek immediate care from an ophthalmologist if there are sudden changes in your vision, such as an increase in floaters, the appearance of "spider webs," flashing lights, sensitivity to light, loss of vision or visual field, progressively worsening eye pain, or increasing discharge/drainage from the eye as these symptoms could be a sign of a more serious issue.

## **General information about the safe and effective use of ENCELTO**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your ophthalmologist for a copy of the information about ENCELTO that is written for healthcare professionals.

You should inform your ophthalmologist that you have an ENCELTO implant inserted prior to any eye examination.

## **What are the ingredients in ENCELTO?**

**Active ingredients:** ENCELTO is an encapsulated cell-based therapy that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line), a neurotrophic factor.

**Inactive ingredients:** ENCELTO contains excipients (Human Endothelial Serum Free Medium (SFM) that may cause sensitivity in some patients.

**Manufactured for:** Treatment of idiopathic macular telangiectasia type 2 (MacTel)

### **Manufactured by:**

Neurotech Pharmaceuticals, Inc.  
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This Patient Information has been approved by the U.S. Food and Drug Administration.

F11002F Rev. 01

Revised: 2025/03