

For adults with idiopathic macular telangiectasia type 2, also known as MacTel



**ENCELTO**<sup>TM</sup>

(revakinagene taroretcel-lwey)

implant, for intravitreal use



Not an actual patient.

# Get to know **ENCELTO**, the first and only FDA-approved treatment for MacTel

## IMPORTANT SAFETY INFORMATION

### 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).

**Please see Important Safety Information on pages 10-14 and full [Prescribing Information](#).**

# About ENCELTO—the first and only FDA-approved treatment for adults with MacTel

## ENCELTO helps to slow the progression of MacTel



**Proven results** in 2 clinical studies with 228 participants



**Promotes survival of the photoreceptors** that could be lost over time due to MacTel



Most side effects were **mild to moderate** in the clinical studies



**A tiny capsule** placed in the eye during a single, outpatient surgical procedure

Please see **Important Safety Information** on pages 10-14 and full [Prescribing Information](#).



Not an actual patient.

## How does ENCELTO work?

- ENCELTO continually releases CNTF into the eye, where your photoreceptors are located
- CNTF is believed to help promote photoreceptor survival

Image not to scale.



— APPROXIMATE SIZE  
6.5 mm

## IMPORTANT SAFETY INFORMATION (cont'd)

**Before receiving ENCELTO, tell your eye surgeon 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 (NSAIDs).

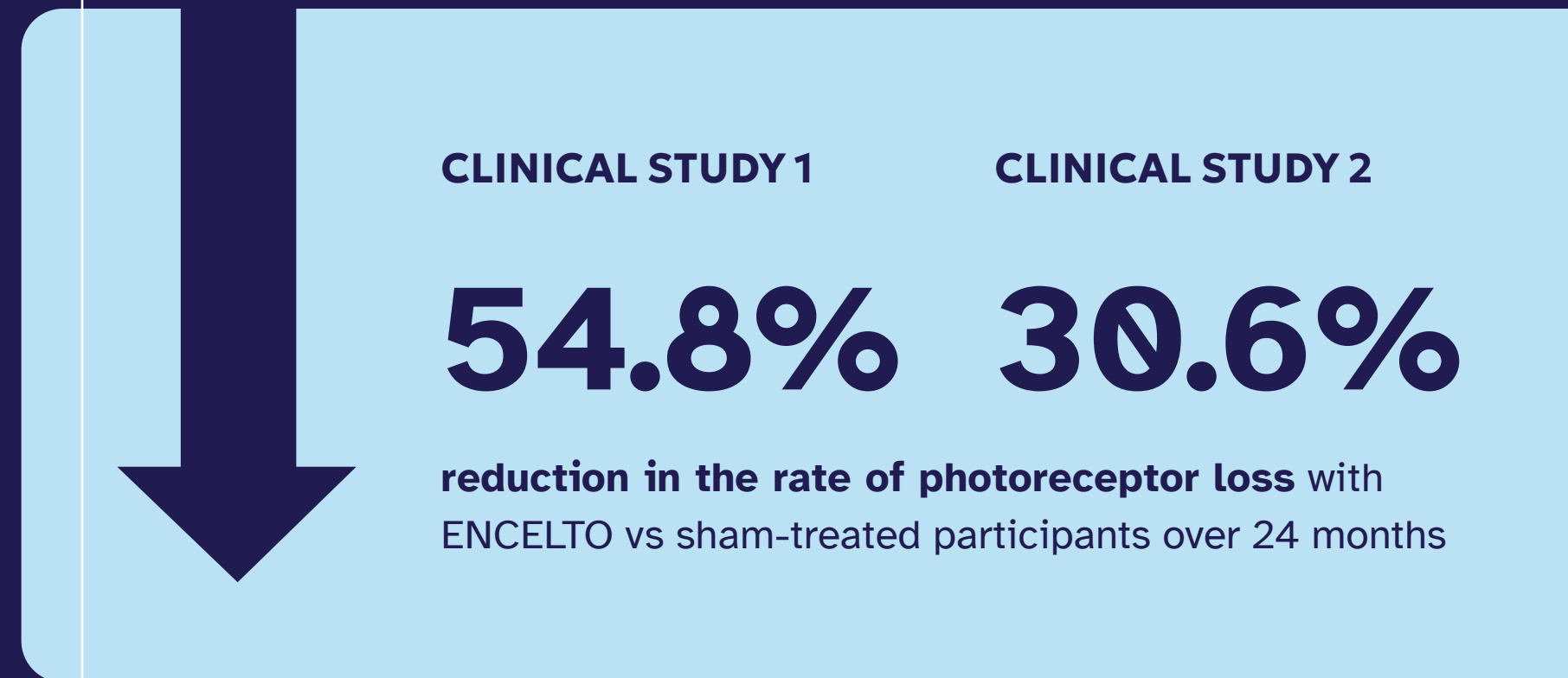
## Proven to slow the rate of photoreceptor loss in 2 clinical studies



Not an actual patient.

- 228 adults diagnosed with MacTel were split into 2 groups:
  - 117 adults received ENCELTO in 1 eye
  - 111 adults received a sham procedure, meaning a non-treatment surgery, in 1 eye
- The studies measured the rate of photoreceptor loss with ENCELTO vs sham-treated participants over 24 months
- Both studies included adults between the ages of 21 and 80 who had been diagnosed with MacTel type 2 in at least 1 eye

Please see Important Safety Information on pages 10-14 and full [Prescribing Information](#).



**While ENCELTO may slow MacTel progression, it cannot restore vision.** If you think ENCELTO might be right for you, talk to your eye care professional as soon as possible.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### How is ENCELTO administered?

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

## Most side effects were mild to moderate in the clinical studies

**It is common to experience the following symptoms after the ENCELTO procedure:**

- Sensation of something in the eye
- Eye redness, irritation, dryness, and/or discharge
- Mild to moderate eye pain or discomfort
- Small spots or shapes that appear in your vision (“floaters”)
- Headache

Before receiving ENCELTO, tell your eye care professional about all your medical conditions, including if you are pregnant or plan to become pregnant. The effects of ENCELTO on unborn babies have not been fully studied.

**No study participants who received ENCELTO had to have the capsule removed because of side effects.**

**Please see Important Safety Information on pages 10-14 and full [Prescribing Information](#).**



**Please be advised that ENCELTO and the surgical procedure have related risks, such as:**

- Eye infection
- Retinal tear and detachment (retina tears and potentially separates from the eye, resulting in vision loss)
- Bleeding within the eye
- Capsule extrusion (ENCELTO begins to work its way out of the eye)
- Suture-related issues (such as irritation or exposure of sutures)
- Temporary or permanent vision loss
- Accelerated cataract formation (clouding of the lens of the eye)
- Delayed ability for the eye to adjust from bright lighting to dark lighting (please be advised that delayed dark adaptation may be experienced for the length of time ENCELTO is surgically placed)

**These are not all the possible side effects of ENCELTO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What should I avoid after placement of ENCELTO?

Immediately postoperative:

- Avoid heavy lifting (over 20 pounds) for 1 week.
- Keep water out of the eye (eg, close your eye while showering) for 1 week.
- Protect your eyes by wearing glasses or protective eyewear during the day and using an eye shield at night for 1 week.
- Do not drive or use machinery until the eye shield has been removed and your eye surgeon informs you that your vision has recovered to an acceptable level.

**ENCELTO**  **connect**™  
(revakinagene taroretcel-lwey)  
implant, for intravitreal use

We're here to help you navigate your treatment journey

If prescribed ENCELTO, you'll be paired with a Patient Access Consultant (PAC)

PACs act as guides, helping adults who are prescribed ENCELTO navigate any access-related questions or concerns that come up during their treatment journey

From prescription to procedure, ENCELTOconnect will be there to guide the way.

Please see Important Safety Information on pages 10-14 and full

8 [Prescribing Information](#).



Not an actual patient.

Your PAC will be with you at every step, providing support based on your unique situation, including:



**Insurance Support**

Verifying insurance coverage and providing guidance on your benefits



**Financial Assistance Options**

Searching for any financial assistance options available to you and helping you apply for those benefits

If you have questions, please call **1-877-ENCELTO** (1-877-362-3586) (Mon-Fri, 8AM-8PM ET) to speak to a PAC.

## 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 rhCNTF. 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 eye surgeon will assess your vision and review your medical history to determine if ENCELTO is the right treatment for you.

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- 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 (NSAIDs).

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removal surgery must also be done by an eye surgeon experienced in vitreoretinal surgery in an operating room as an outpatient surgery.

## What should I avoid after placement of ENCELTO?

Immediately postoperative:

- Avoid heavy lifting (over 20 pounds) for 1 week.
- Keep water out of the eye (eg, close your eye while showering) for 1 week.
- Protect your eyes by wearing glasses or protective eyewear during the day and using an eye shield at night for 1 week.
- Do not drive or use machinery until the eye shield has been removed and your eye surgeon informs you that your vision has recovered to an acceptable level.

Postoperative care:

- Use a topical antibiotic solution at a frequency of 1 drop 4 times a day for 7 days.

## IMPORTANT SAFETY INFORMATION (cont'd)

- Use a steroid drop taper of prednisolone acetate 1% (or equivalent) starting the day after surgery with the following taper:
  - 1 drop 4 times a day for the first 7 days;
  - 1 drop 3 times a day for the next 7 days;
  - 1 drop 2 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.

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

Please follow all postoperative instructions given by your eye surgeon and ensure you attend all follow-up visits as recommended.

#### **Potential side effects:**

Please be advised that ENCELTO and the surgical insertion have 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 (eg, 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 (ie, 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

**Please see Important Safety Information on pages 10-14 and full [Prescribing Information](#).**

## IMPORTANT SAFETY INFORMATION (cont'd)

### When to Seek Eye Surgeon Advice

You are to seek immediate care from an eye surgeon 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.

**Call your eye surgeon for medical advice about side effects.**

**You may report side effects to the FDA at 1-800-FDA-1088.**

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**Sign up to receive ENCELTO information and updates**

