

ZEVASKYN is made from your own skin cells to deliver long-lasting wound healing-even in tough RDEB wounds*

 81% of ZEVASKYN-treated wounds healed by 50% or more when measured at 6 months[†]

*Wounds treated had remained open for at least 6 months.

[†]ZEVASKYN-treated wounds were compared to similar wounds treated with typical wound care in 11 RDEB patients as part of a clinical trial. 81% of ZEVASKYN-treated wounds (35 of 43) healed by 50% or more vs 16% of matched control wounds (7 of 43).

WHAT IS ZEVASKYN (ZEE-vah-skin)?

ZEVASKYN™ (prademagene zamikeracel) is a type of gene therapy made from your own skin cells that is surgically applied to treat wounds in both children and adults who have recessive dystrophic epidermolysis bullosa (RDEB).

IMPORTANT SAFETY INFORMATION

Serious allergic reactions to ZEVASKYN can occur. Get medical help right away if you or your child experience symptoms like itching, swelling, hives, difficulty breathing, runny nose, watery eyes, or nausea. In rare cases, a severe reaction called anaphylaxis may happen.

Please see additional Important Safety Information on page 13 and full Prescribing Information.



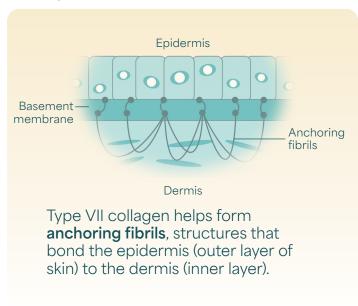
See long-term follow-up images

People with RDEB need long-lasting wound healing



Healthy skin cells contain a gene (*COL7A1*) that tells the body how to produce type VII collagen (type 7 collagen)—a protein needed to bond layers of the skin together. In RDEB, the body produces little to no working type VII collagen due to a mutation in both copies of the *COL7A1* gene.

Healthy skin



RDEB skin



These wounds can be various sizes, cover a significant body surface area, and be a constant source of pain and itch. RDEB wounds are at risk of getting infected and developing a type of skin cancer called squamous cell carcinoma (SCC).



Goals of wound treatment:

- Provide durable wound healing
- Reduce pain and itch

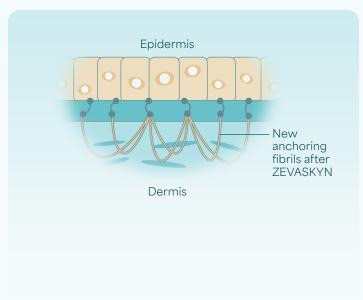
ZEVASKYN is designed for longlasting wound healing with a single surgical application



What is it?

ZEVASKYN gene-modified cellular sheets are made from your own skin cells and surgically applied.

ZEVASKYN-treated skin



How is it made?

Two punch biopsies are taken from your skin and sent to Abeona Therapeutics[®]. The cells are then genetically modified to produce working type VII collagen. Over a few weeks, the cells are grown into credit card-sized ZEVASKYN cellular sheets.

How is it applied?

In a single surgery, ZEVASKYN sheets are applied to your wounds under general or other appropriate anesthesia.

How does it work?

ZEVASKYN works by producing functional type VII collagen in your treated wounds. This forms anchoring fibrils that bond together the epidermal and dermal layers of your skin.

IMPORTANT SAFETY INFORMATION

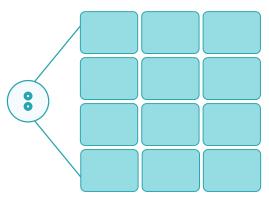
There is a potential risk that treatment with ZEVASKYN may contribute to the development of cancer because of how the therapy works. Patients should be monitored for the rest of their lives to check for any signs of cancer.

ZEVASKYN provides unprecedented coverage for RDEB wounds in a single surgical session

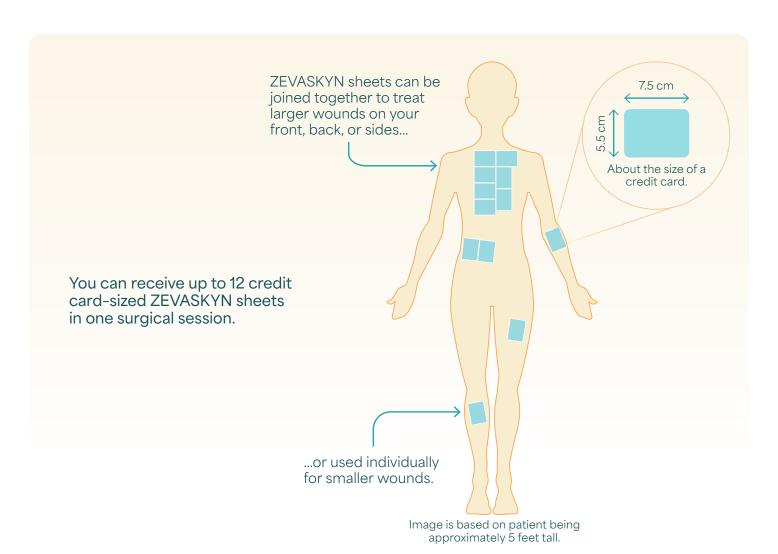


How much wound coverage can ZEVASKYN provide?

Your two 8 mm punch biopsies (the size of 2 small peas) expand up to 12 credit card-sized sheets.



Not to scale.



IMPORTANT SAFETY INFORMATION

ZEVASKYN is made using human and animal materials. Although these materials are tested before use, the risk of passing on infections cannot be eliminated.

ZEVASKYN was studied in chronic RDEB wounds of various shapes and sizes



A clinical study (VIITAL) assessed how well ZEVASKYN works

The clinical study evaluated 43 ZEVASKYN-treated wounds in 11 patients over 6 months. Each wound was compared to a matched control wound of similar size and chronicity in the same patient.* A total of 86 wounds were evaluated across all patients.

- Ages of patients treated in the study ranged from 6 to 40 years old
- Wounds studied had been open for a median duration of 5 years with a range of 6 months to 21 years[†]
- Wound size had to be at least 20 cm²
- Patients in the clinical study received a median (middle value) of 6 ZEVASKYN sheets (range of 3-6 sheets), which was the maximum number allowed in the clinical study





At 6 months, the study measured:

- Wound healing
- Pain reduction
- Itch reduction

IMPORTANT SAFETY INFORMATION

The most common side effects are pain from the procedure and itching.

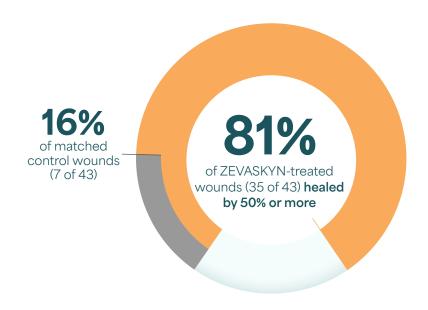
^{*43} control wounds (those not treated with ZEVASKYN) received standard of care treatment (eg, bandages and palliative care).

†Median is the middle number in a group of numbers arranged from lowest to highest.



Significant wound healing with ZEVASKYN at 6 months





- Complete healing seen in 16% of ZEVASKYN-treated wounds vs none of the matched control wounds*
- ~2 out of 3 ZEVASKYN-treated wounds (28 of 43) healed by 75% or more vs 7% of matched control wounds (3 of 43)

ZEVASKYN-treated wounds showed noticeable **healing within 6 weeks**, compared to fewer control wounds. This analysis was based on a subset of wounds (28/43) that were assessed at 6 weeks.[†]

IMPORTANT SAFETY INFORMATION

You may feel pain or itching at the treated area as it heals. Contact your doctor if you have: fever, increased drainage, worsening pain or swelling, or any other symptoms at or near the treated area.

^{*}Complete wound healing was defined as the new skin completely covered, with no drainage, no damage of the treated skin, and no major scabbing.

[†]Not all wounds were evaluated early at 6 weeks. The study was not specifically designed to fully measure these results, so they should be interpreted carefully.

ZEVASKYN: Proven to reduce pain in treated wounds



At 6 months (VIITAL study)

Reduction in pain (using a 0-10 scale)*



Reduction in itch (using a 0-10 scale)[†]





Oh, it was bad [before treatment with ZEVASKYN]. It was constantly itching, and the medicine wasn't helping. And then [after treatment with ZEVASKYN, there] was less itching, less wounds, and less pain, too. When it heals [after surgery], I don't feel itching.

-Guadalupe, treated with ZEVASKYN

Individual results may vary.

IMPORTANT SAFETY INFORMATION

Do not disturb the surgical dressing for 5–10 days, unless your doctor tells you otherwise.

^{*}Pain reduction was measured on a 0-10 scale before and after treatment (following wound dressing change). Pain reduction was measured using the Wong-Baker FACES® Pain Rating Scale that is used to help people communicate the severity of their pain by choosing a face that best matches their experience.

[†]Itch severity was measured using the Worst Itch-Numeric Rating Scale (WI-NRS), ranging from 0 (no itch) to 10 (worst itch imaginable).

Example of wound healing after long-term follow-up



See what healing with ZEVASKYN can look like long term

In a separate clinical study of 7 patients with RDEB, 38 chronic wounds were assessed long term after treatment with ZEVASKYN. The study did not evaluate ZEVASKYN-treated wounds against control wounds or placebo.

 Patients were followed for a median (middle value) of 6.9 years (range 4-8 years), with a planned follow-up of 15 years*

Because the study did not include a control group or placebo for comparison, it was not designed to determine whether the observed effects were due to ZEVASKYN.



Individual results may vary.



When the nurse and doctor took off the bandage and I saw that new skin, when I saw it I just cried.

-Jessica, mom of Geovanna, who was treated with ZEVASKYN Individual results may vary.



Hear from patients, caregivers, and EB experts as they share their experiences with ZEVASKYN.

EB=epidermolysis bullosa.

*Median is the middle number in a group of numbers arranged from lowest to highest.

IMPORTANT SAFETY INFORMATION

Keep the dressing(s) dry. Do not soak the treated area(s) in water (like in a bath or pool) until the gauze backing falls off of the treated area(s), approximately 2–3 weeks after the surgery.

ZEVASKYN can close even tough RDEB wounds



See what healing with ZEVASKYN treatment can look like at 6 months



Wound images from different patients in the study. Individual results may vary.

IMPORTANT SAFETY INFORMATION

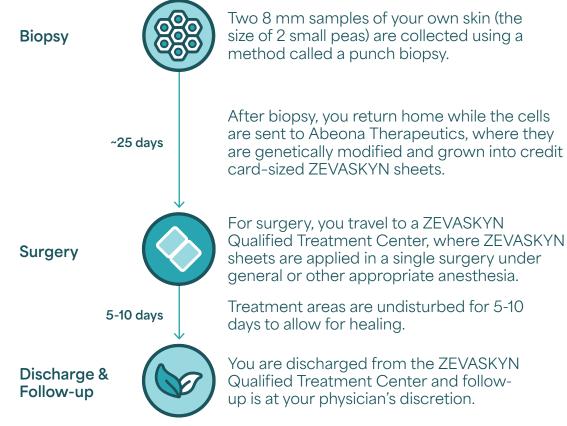
ZEVASKYN is made from your own skin cells. In rare cases, the manufacturing process may not work. If this happens, your doctor may suggest taking another skin biopsy to repeat the manufacturing process.



ZEVASKYN is surgically applied to wounds at a ZEVASKYN Qualified Treatment Center



What to expect during the treatment journey



Connect with a patient or caregiver who has experience with ZEVASKYN treatment



Whether you are just beginning to explore your options or are ready to take the next step, the **Strong Together Network** lets you talk to someone who has been treated or cares for a loved one treated with ZEVASKYN.

Call Abeona Assist at <u>1-855-ABEONA-1</u> (1-855-223-6621) Monday through Friday, 9:00 AM to 6:30 PM ET to get connected.

IMPORTANT SAFETY INFORMATION

Serious allergic reactions to ZEVASKYN can occur. Get medical help right away if you or your child experience symptoms like itching, swelling, hives, difficulty breathing, runny nose, watery eyes, or nausea. In rare cases, a severe reaction called anaphylaxis may happen.

Abeona Assist is your dedicated support partner every step of the way



If you're considering ZEVASKYN or have questions, Abeona Assist is here to help



ZEVASKYN treatment pathway

Our trained Patient Navigators* provide information on ZEVASKYN, what to expect, and next steps to take.



Coverage review and financial assistance[†]

Our team works to explore your benefits, identify out-of-pocket costs, and provide information about access and reimbursement.



Travel and logistical support[†]

Our team helps coordinate travel to a ZEVASKYN Qualified Treatment Center and provides support during your stay.



To locate a ZEVASKYN Qualified Treatment Center, get your questions answered, and enroll in Abeona Assist:

Call 1-855-ABEONA-1 (1-855-223-6621)

Monday-Friday 9:00 AM-6:30 PM ET



Email mynavigator@abeonaassist.com



Visit abeonaassist.com



^{*}Patient Navigators do not direct patient care or provide medical advice.

[†]Eligibility requirements apply.



Established safety profile



ZEVASKYN has been evaluated in 43 large, chronic wounds in 11 patients

- The most common side effects are pain from the procedure (3 of 11 patients) and itching (1 of 11 patients)
- No grade 3 side effects were reported*

Serious allergic reactions to ZEVASKYN can occur, including rare cases of anaphylaxis. ZEVASKYN may increase the risk of cancer due to how it works; lifelong monitoring is recommended. It is made from human and animal materials, and although tested, the risk of infection transmission cannot be completely ruled out. Please see additional Important Safety Information on the next page.

Additional long-term safety from clinical studies

- In 99 large, chronic ZEVASKYN-treated wounds across 18 patients:
 - Median (middle value) follow-up of 3 years and 2 months after treatment (range of 12 months to 11 years)[†]
- No cases of squamous cell carcinoma (SCC) were reported in ZEVASKYN-treated wounds
 - SCC is a type of skin cancer that develops in the epidermis or outer layer of the skin
 - SCC was observed in non-treated sites in 4 patients

^{*}Grade 3 side effects are considered severe and medically significant, but not immediately life-threatening. They can interfere with daily activities, limit self-care, and may even require or prolong hospitalization.

^{*}Median is the middle number in a group of numbers arranged from lowest to highest.

Indication and Important Safety Information



WHAT IS ZEVASKYN?

ZEVASKYN™ (prademagene zamikeracel) is a type of gene therapy made from your own skin cells that is surgically applied to treat wounds in both children and adults who have recessive dystrophic epidermolysis bullosa (RDEB).

IMPORTANT SAFETY INFORMATION

- Serious allergic reactions to ZEVASKYN can occur. Get medical help right away if you or your child experience symptoms like itching, swelling, hives, difficulty breathing, runny nose, watery eyes, or nausea. In rare cases, a severe reaction called anaphylaxis may happen.
- There is a potential risk that treatment with ZEVASKYN may contribute to the development of cancer because of how the therapy works. Patients should be monitored for the rest of their lives to check for any signs of cancer.
- ZEVASKYN is made using human and animal materials. Although these materials are tested before use, the risk of passing on infections cannot be eliminated.
- The most common side effects are pain from the procedure and itching.

This is not a complete list of side effects. Call your care team for medical advice about side effects. You may report side effects to Abeona at <u>1-844-888-2236</u> or FDA at <u>1-800-FDA-1088</u> or <u>www.fda.gov/medwatch</u>.

POST-APPLICATION CARE

- You may feel pain or itching at the treated area as it heals. Contact your doctor
 if you have: fever, increased drainage, worsening pain or swelling, or any other
 symptoms at or near the treated area.
- Do not disturb the surgical dressing for 5–10 days, unless your doctor tells you otherwise.
- Keep the dressing(s) dry. Do not soak the treated area(s) in water (like in a bath or pool) until the gauze backing falls off of the treated area(s), approximately 2-3 weeks after the surgery.

PRODUCT MANUFACTURING

 ZEVASKYN is made from your own skin cells. In rare cases, the manufacturing process may not work. If this happens, your doctor may suggest taking another skin biopsy to repeat the manufacturing process.



Questions to ask your EB doctor



Below is a list of things people with RDEB and their caregivers may want to ask about treatment with ZEVASKYN.

- Am I a good candidate for ZEVASKYN?
- Which of my wounds will ZEVASKYN be applied to?
- Is treatment with ZEVASKYN available only at ZEVASKYN Qualified Treatment Centers?
- Where is the nearest ZEVASKYN Qualified Treatment Center?
- How will I know if ZEVASKYN is working?
- How long will my wounds take to heal after treatment with ZEVASKYN?
- What will my skin look like after ZEVASKYN?
- What support is available for patients who are considering or will be receiving treatment with ZEVASKYN?
- Is financial support available for treatment with ZEVASKYN?
- What side effects can happen with ZEVASKYN?
- How is ZEVASKYN different from other treatment options?
- How will I care for the area treated with ZEVASKYN after surgery?
- How long will my wounds stay healed after treatment with ZEVASKYN?

Notes



You might find it helpful to write down any additional questions that may arise.	

IMPORTANT SAFETY INFORMATION

There is a potential risk that treatment with ZEVASKYN may contribute to the development of cancer because of how the therapy works. Patients should be monitored for the rest of their lives to check for any signs of cancer.



Strong Bonds Stand the Test of Time

ZEVASKYN is made from your own skin cells to deliver long-lasting wound healing-even in tough RDEB wounds*

 81% of ZEVASKYN-treated wounds achieved 50% or more healing when measured at 6 months[†]



*Wounds treated had remained open for at least 6 months.

[†]ZEVASKYN-treated wounds were compared to similar wounds treated with typical wound care. 81% of ZEVASKYN-treated wounds (35 of 43) healed by 50% or more vs 16% of matched control wounds (7 of 43).

See long-term follow-up images

Visit zevaskyn.com



ZEVASKYN treatment has helped me a lot, like not having open wounds, not having to do bandages, not having to worry about infections in that area, it makes such a difference.

-Noelle, treated with ZEVASKYN

Individual results may vary.



For more information, please scan the code or call Abeona Assist at 1-855-ABEONA-1 (1-855-223-6621). Monday-Friday 9:00 AM-6:30 PM ET

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