

NOW APPROVED

For people aged 6 months and older with dystrophic epidermolysis bullosa (DEB)

Big or small, each wound healed is a **victory**

VYJUVEK is the **FIRST and ONLY** treatment that addresses the **genetic cause** of DEB to provide **powerful wound healing** in a topical gel.

See **VYJUVEK** study results within.

INDICATION AND USAGE

VYJUVEK is a topical gel used to treat wounds in patients 6 months and older with dystrophic epidermolysis bullosa (DEB).

IMPORTANT SAFETY INFORMATION

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours. If accidentally exposed to the VYJUVEK gel, clean the affected area.

Please see Important Safety Information throughout and click here for full [Prescribing Information](#).

Vyjuvek[™]
beremagene geperpavec-svdt
5x10⁹ PFU/mL single-use vial

About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

[Important Safety Information](#)

[Prescribing Information](#)

Emily,
Living with DEB

Dystrophic epidermolysis bullosa (DEB) is a type of epidermolysis bullosa (EB), a group of serious genetic blistering disorders

The most common symptom of DEB is fragile skin. This can lead to blisters, wounds, skin infections, and scarring.

- ▶ There are 2 types of DEB: dominant and recessive
- ▶ Whether you have dominant DEB (DDEB) or recessive DEB (RDEB), wounds can be large or small, take a long time to heal or not heal at all, and reopen after healing
- ▶ Beyond symptoms you can see on the skin, DEB can affect other organs and body systems, including the eyes, mouth, gastrointestinal tract, and urinary tract
- ▶ In addition to physical symptoms, people with DEB and those who care for them can face significant emotional, mental, and financial burdens

All DEB wounds should be taken seriously. It's possible for any DEB wound to develop complications, such as infections or a certain type of aggressive skin cancer called squamous cell cancer (SCC).

[The Genetic Cause of DEB >>](#)

About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

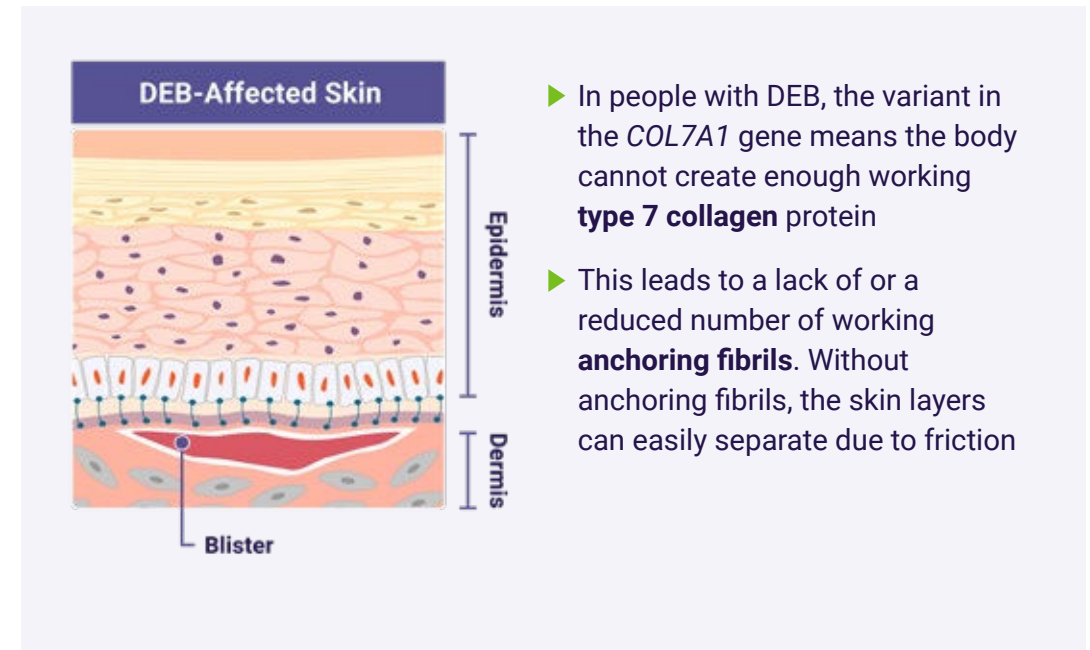
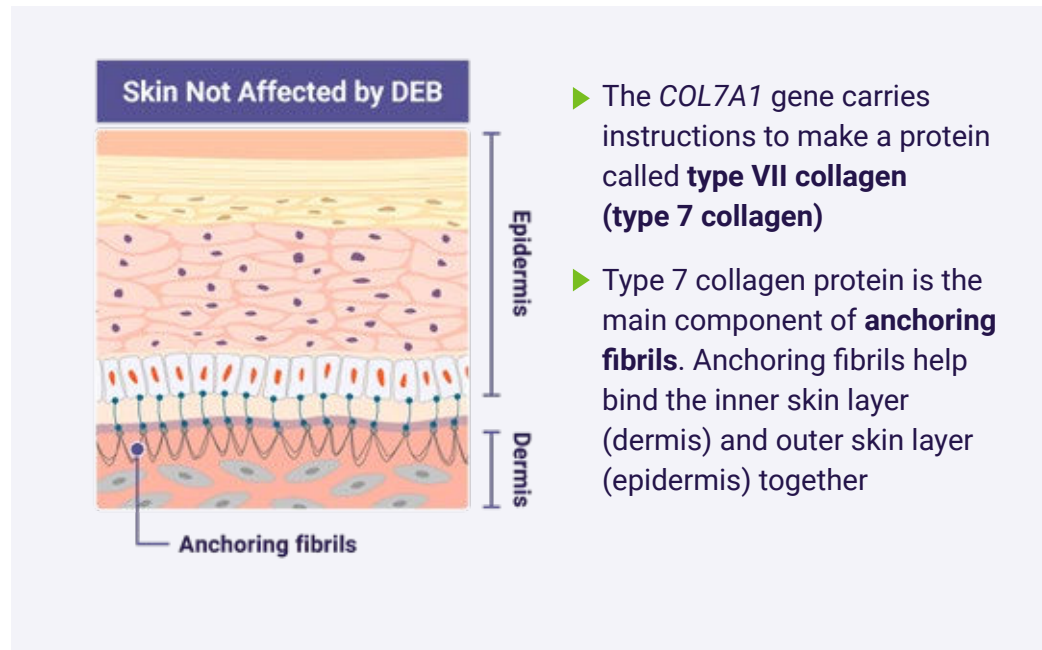
Treatment
with VYJUVEK

Resources
and Support

Summary

DEB is a genetic condition caused by variants in a gene called *COL7A1*

Genes carry instructions that tell the body how to build specific proteins. Changes in the instructions are called gene mutations or variants.



Adapted from De Rosa L, Latella MC, Secone Seconetti A, et al. *Cold Spring Harb Perspect Biol.* 2020.

[Learn About a Treatment Option That Addresses the Genetic Cause of DEB >](#)

About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

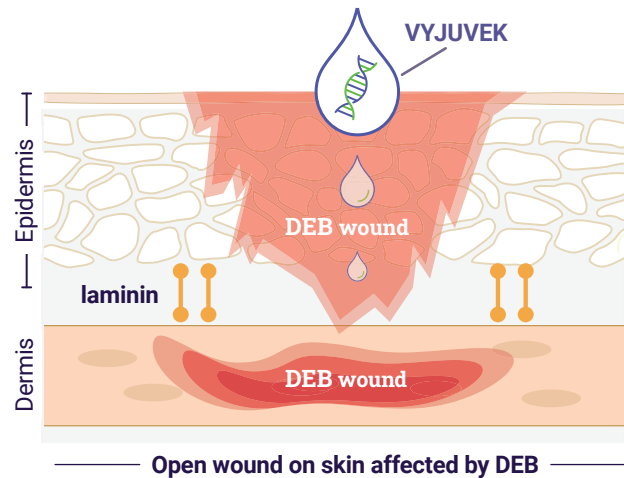
Safety

Treatment
with VYJUVEK

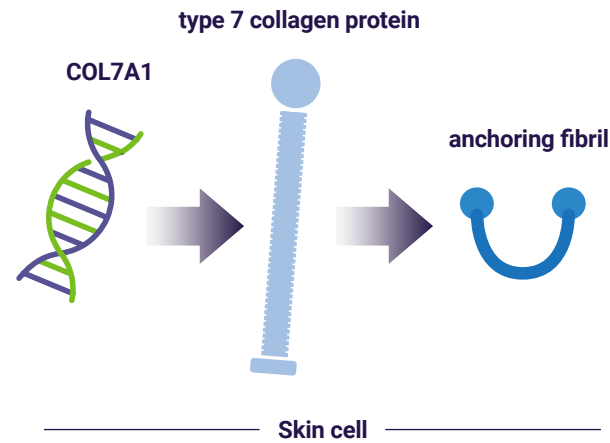
Resources
and Support

Summary

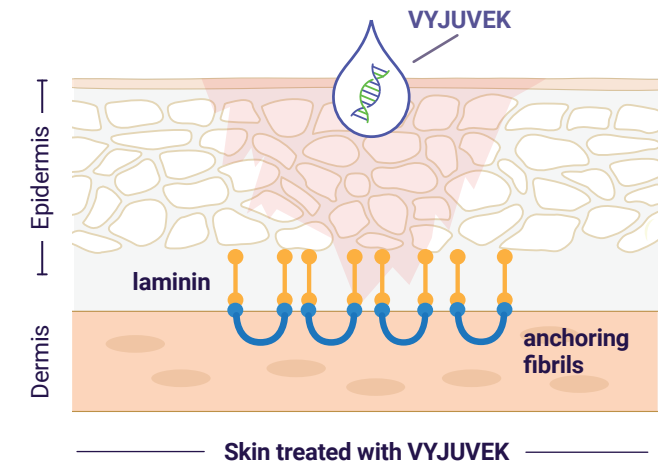
VYJUVEK is a topical therapy that delivers new *COL7A1* genes directly to DEB skin wounds to promote wound healing



VYJUVEK delivers new *COL7A1* genes directly to skin cells in DEB wounds.



These *COL7A1* genes restore the ability of those cells to make functional **type 7 collagen** protein and form **anchoring fibrils**.



Anchoring fibrils bind the inner skin layer (dermis) and outer skin layer (epidermis) together and promote wound healing.

[How VYJUVEK Was Studied >](#)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

[Important Safety Information](#)

[Prescribing Information](#)

Wound healing with VYJUVEK was assessed in a clinical study (GEM-3 study) of patients with DEB

The goal of the study was to evaluate complete wound healing (100% closure).

- ▶ This study included 31 people, ranging in age from 1 to 44 years old, with dominant DEB or recessive DEB
- ▶ For each person, 2 similar wounds were chosen. One was treated with VYJUVEK and the other received placebo
 - Placebo is a treatment containing no medication that was given to participants the same way as VYJUVEK
- ▶ The main measure of the study was complete wound healing at **6 months**
- ▶ Treatments were applied weekly until wounds were completely healed. Treatment resumed if wound reopened
- ▶ After completion of the GEM-3 study, patients were allowed to enroll in the Open Label Extension study*



*The Open Label Extension study was designed to assess long-term safety.

IMPORTANT SAFETY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

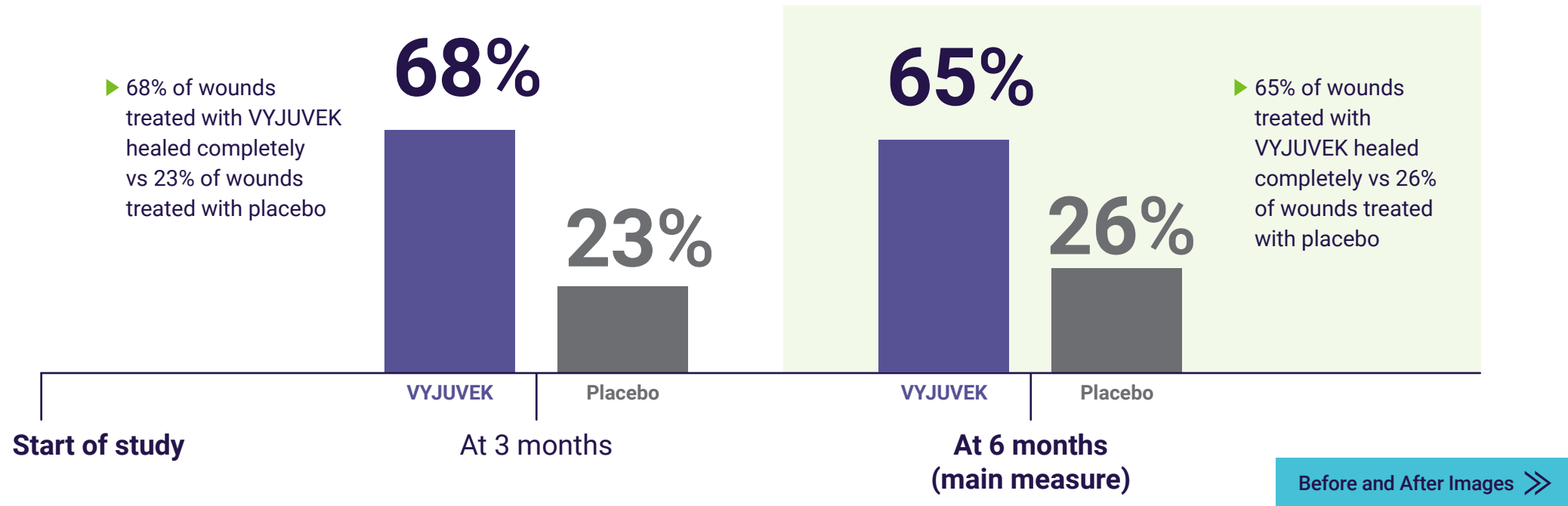
Summary

[Important Safety Information](#)

[Prescribing Information](#)

VYJUVEK achieved significantly greater complete wound healing (100% closure) compared with placebo

Complete wound healing in 31 patients at 3 and 6 months



IMPORTANT SAFETY INFORMATION (cont'd)

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. **Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to the Sponsor at 1-844-557-9782.**

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

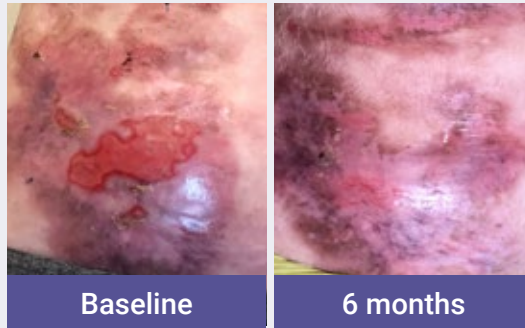
Summary

[Important Safety Information](#)

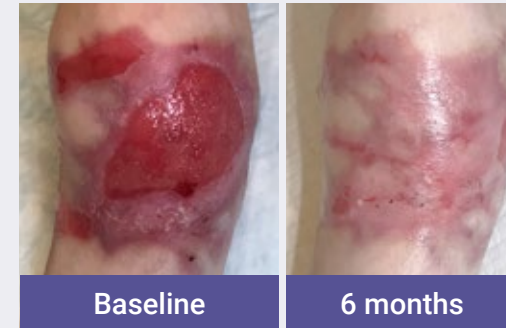
[Prescribing Information](#)

Before and after treatment with VYJUVEK—in small, medium, and large wounds

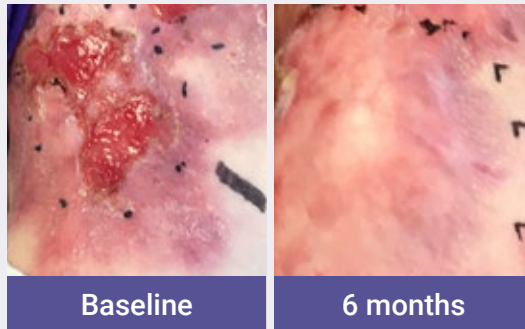
Patient A
Small Wound
Lower Abdomen
Pediatric Female



Patient B
Medium Wound
Knee
Pediatric Male



Patient C
Medium Wound
Shoulder Blade
Adult Female



Patient D
Large Wound
Back
Adult Male

Complete wound closure was achieved 2 months into the Open Label Extension study following completion of the GEM-3 study.*



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[More Wound Healing Data >>](#)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

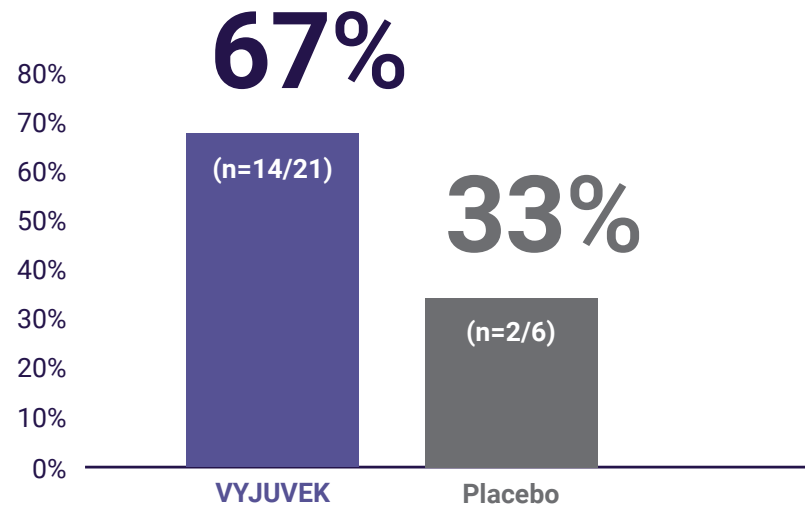
Treatment
with VYJUVEK

Resources
and Support

Summary

Of the wounds treated with VYJUVEK that were healed at 3 months, 67% (14/21) were also healed at 6 months*

Wounds healed at 3 months also healed at 6 months



*Data on file.

- ▶ In an analysis done after the study was completed, wounds that were completely healed at 3 months were then reevaluated at 6 months to see what percentage were completely healed
- ▶ These analyses were conducted after the study was completed in an unplanned exploratory analysis of both VYJUVEK-treated and placebo-treated wounds. These findings are based on a limited sample size and should be interpreted carefully

Safety >

IMPORTANT SAFETY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

VYJUVEK was well tolerated by study participants

Most common side effects in 31 people treated with VYJUVEK	
Side effects	Number of people (%)
Itching	3 (10)
Chills	3 (10)
Redness	2 (6)
Rash	2 (6)
Cough	2 (6)
Runny nose	2 (6)

No study participants stopped treatment with VYJUVEK due to side effects.

[Treatment with VYJUVEK >](#)

IMPORTANT SAFETY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

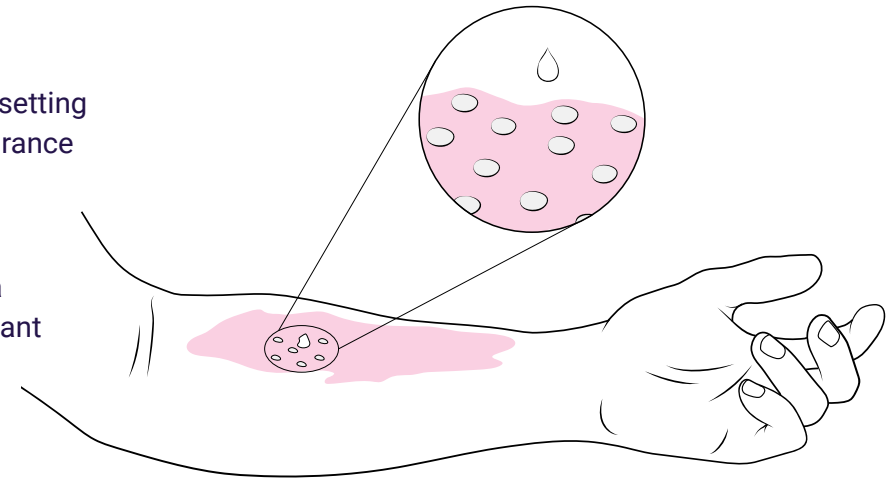
Summary

Treatment with VYJUVEK

VYJUVEK gel is applied topically once weekly to promote wound healing.

Administration

- ▶ Only a healthcare professional can prescribe and apply VYJUVEK gel. There are special storage and preparation requirements with VYJUVEK
- ▶ VYJUVEK can be administered by a healthcare professional at a healthcare professional setting (for example, a clinic) or home setting, depending on your doctor's instructions, your insurance plan coverage, and your preference
- ▶ To begin administration, the wound must be unwrapped
- ▶ VYJUVEK gel is then applied in droplets that are evenly spaced (1 cm by 1 cm apart) on a wound until the maximum weekly dose is reached. Wounds are covered by a water-resistant dressing. Standard dressings are then applied on top
- ▶ Routine dressing changes can resume after approximately 24 hours
 - Avoid touching treated wounds and dressings for the first 24 hours after application. In case accidental contact happens, flush the affected area with clean water for at least 15 minutes
 - Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from first dressing change and dispose of disinfected bandages in a separate sealed plastic bag in household waste. Dispose of subsequent used dressings in a sealed plastic bag in household waste



Treatment with VYJUVEK (cont'd) >>>

IMPORTANT SAFETY INFORMATION (cont'd)

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. **Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to the Sponsor at 1-844-557-9782.**

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

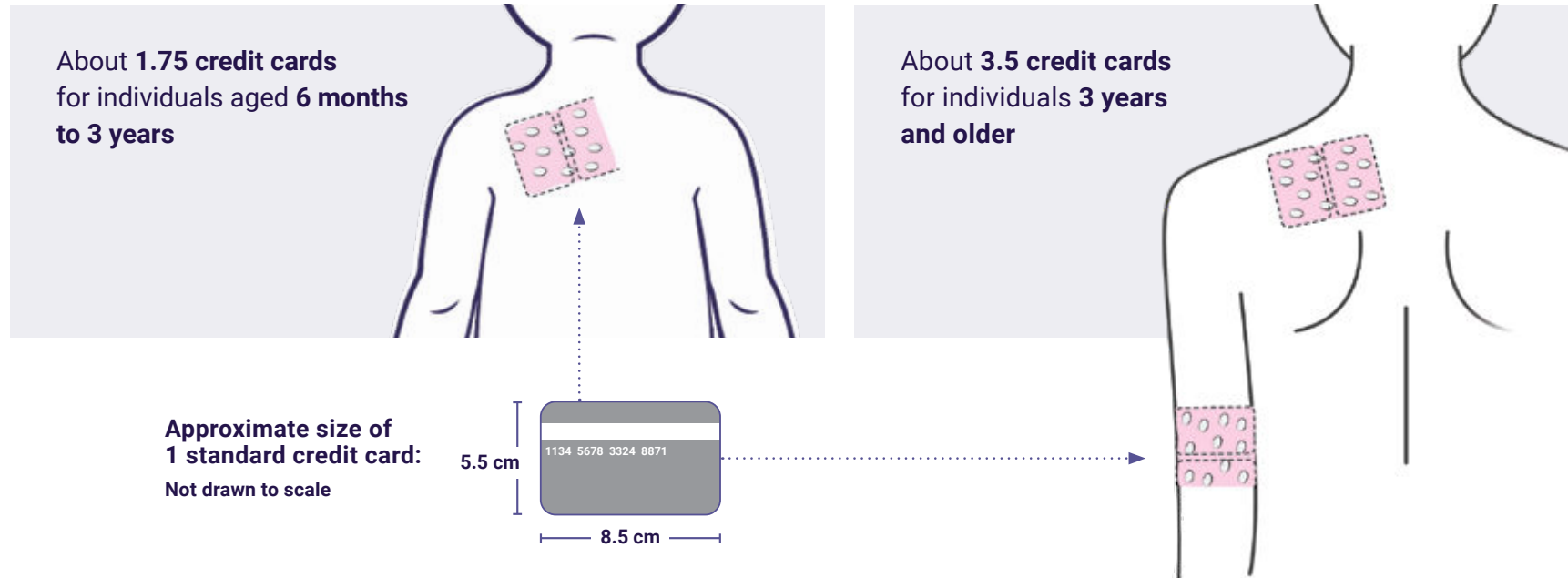
[Important Safety Information](#)

[Prescribing Information](#)

Treatment with VYJUVEK (cont'd)

VYJUVEK gel is applied topically once weekly to promote wound healing.

- ▶ Each maximum weekly dose of VYJUVEK gel covers a total wound surface area similar to the size of*:



*This information is for illustrative purposes only. The total surface area covered may vary. Your healthcare provider will follow the 1 cm x 1 cm application process based on the full prescribing information.

[Creating a Treatment Plan >>](#)

IMPORTANT SAFETY INFORMATION

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

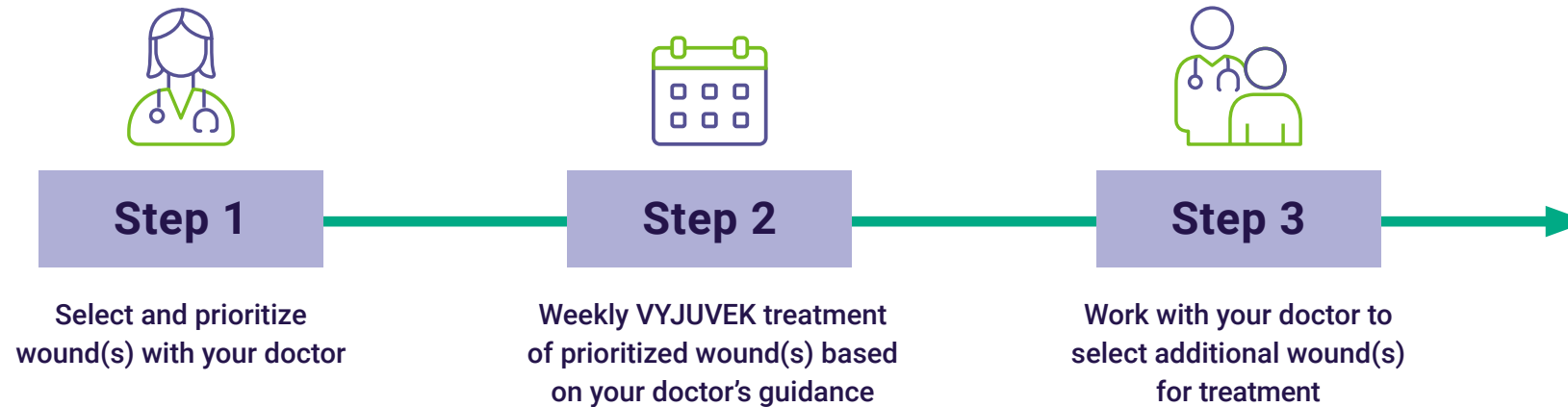
Summary

[Important Safety Information](#)

[Prescribing Information](#)

Creating a VYJUVEK treatment plan

Because of the maximum weekly dose, it may not be possible to apply VYJUVEK gel to all wounds during your appointment—you and your doctor can work together to create a prioritized wound treatment plan.



It is important to continue weekly treatment of each treated wound(s) until it is fully healed. Once completely healed, other wound(s) can be treated with VYJUVEK.

[Resources and Support >](#)

IMPORTANT SAFETY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

[Important Safety Information](#)

[Prescribing Information](#)

Krystal Connect is a personalized patient support program to help you throughout your treatment journey

Whether you're considering treatment, ready to start, or looking for more information about DEB, Krystal Connect is here to help you.

When you contact and enroll in Krystal Connect, you will be connected to a dedicated team. Your team is available to:

- ▶ Provide education about VYJUVEK and DEB
- ▶ Help you understand your insurance coverage through benefits investigation
- ▶ Inform you about financial assistance programs for eligible patients
- ▶ Support treatment planning and administration
- ▶ Provide information to help you locate a treating doctor in your area



Sign up for more information at [VYJUVEK.com](https://www.vyjuvek.com) or call 1-844-5-KRYSTAL.

[More Krystal Connect Resources >>](#)

IMPORTANT SAFETY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

[Important Safety Information](#)

[Prescribing Information](#)

Meet your Krystal Connect Team

When starting VYJUVEK, you may have questions about your treatment, cost and insurance coverage, or even about DEB.

While your doctor is your main resource, Krystal Connect can help answer your questions and assist you throughout the treatment journey. Your dedicated team includes:



Community Education Liaisons (CELs)

CELs have backgrounds in nursing or genetic counseling. They help answer questions about DEB and treatment with VYJUVEK. They can share information about programs and events tailored to the DEB community.



Patient Access Liaisons (PALs)

Connect to a PAL for help with treatment coordination. PALs help with a broad range of topics, such as insurance coverage and financial assistance. PALs are experts in health insurance and understanding the healthcare system.

CELs and PALs do not direct patient care or provide medical advice.



Sign up for more information at [VYJUVEK.com](https://www.vyjuvek.com)
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Summary >

IMPORTANT SAEFTY INFORMATION (cont'd)

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

Experience VYJUVEK: the **FIRST** and **ONLY** treatment that

- ▶ Addresses the **genetic cause of DEB**
- ▶ Provides **powerful wound healing** in a topical gel

Ask your doctor about VYJUVEK.

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Sign up for more information
at VYJUVEK.com or call
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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary

[Important Safety Information](#)

[Prescribing Information](#)

Indication and Usage, and Important Safety Information

INDICATION AND USAGE

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About DEB

How Does
VYJUVEK Work?

Wound Healing
Results

Safety

Treatment
with VYJUVEK

Resources
and Support

Summary