Diabetic Neuropathic Ulcers—Recognizing the Significant Burden and Reviewing a Treatment Option

Speaker: Dot Weir, RN, CWON, CWS
Osceola Regional Medical Center
Wound Healing Center

Location: University of Toledo Medical Center
3000 Arlington Rd
Toledo, OH 43614
419/383-3547

Date: Wednesday, July 15, 2015 at 12:00 PM

This discussion will cover:
- The prevalence and potential severity of lower extremity diabetic neuropathic ulcers
- The importance of good ulcer care practices
- REGRANEX® Gel—the first and only FDA approved platelet-derived growth factor therapy for diabetic neuropathic ulcers

Registration
If you wish to attend, please log on to:
www.pharmethod.com/Smith-Nephew/Register
Program ID: 22026
Or call Lindsey Steel 248/494-1816

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED RATE OF MORTALITY SECONDARY TO MALIGNANCY
An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of REGRANEX® Gel in a postmarketing retrospective short study. REGRANEX® Gel should only be used when the benefits can be expected to outweigh the risks. REGRANEX® Gel should be used with caution in patients with known malignancy.

Indications and Usage
REGRANEX® (becaplermin) Gel is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. REGRANEX® Gel is indicated as an adjunct to, and not a substitute for, good ulcer care practices.

Limitations of Use
- The efficacy of REGRANEX® Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers
- The effects of REGRANEX® Gel on exposed joints, tendons, ligaments, and bone have not been established in humans
- REGRANEX® Gel is a non-sterile, low bioburden preserved product that should not be used in wounds that close by primary intention
- REGRANEX® Gel is contraindicated in patients with known neoplasm(s) at the site(s) of application. REGRANEX® Gel is contraindicated in patients with known hypersensitivity to any component of the product (e.g., parabens)

Malignancies distant from the site of application have been reported in both a clinical study and in postmarketing use.

In clinical trials, erythematous rashes occurred in 2% of patients treated with REGRANEX® Gel or placebo; none occurred in patients receiving good ulcer care alone. Burning sensation at the site of application and erythema have been reported during post-approval use of REGRANEX® Gel.

Please see Full Prescribing Information on subsequent pages.
For more information, please visit www.Regranex.com.


Study Design: The efficacy and safety of REGRANEX® Gel were studied in 382 patients with type 1 or type diabetes in a multicenter, double-blind, parallel-group, placebo-controlled trial. Patients had at least one full thickness chronic ulcer of the lower extremity. After sharp debridement of the ulcer, patients were randomized to receive REGRANEX® Gel or placebo gel, in conjunction with good ulcer care, until complete wound closure was achieved or for a maximum of 20 weeks. To assess rate of closure, study visits were scheduled weekly for Visits 2–6 and every other week after Visit 6.4

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INDICATIONS AND USAGE

X Gel contains becaplermin, a human platelet-derived growth factor is indicated for the treatment of lower extremity diabetic ulcers that are nonhealing or which are healing in an unacceptable manner due to arterial insufficiency.

DOSE AND ADMINISTRATION

For topical use, not for oral, opthalmic or intravaginal use. This product may be applied to the skin up to twice daily, or as directed by the physician. Becaplermin (X Gel) can be applied to the ulcer surface morning and then again at bedtime. Be sure to apply X Gel to all areas of the ulcer to be treated. Be sure to wash hands after applying X Gel to the ulcer.

APPLICATION IN NONHEALING DIABETIC ULCERS

For the treatment of nonhealing diabetic ulcers, apply Becaplermin (X Gel) to the ulcer surface up to twice daily, or as directed by the physician.

APPLICATION IN PERIPHERAL VASCULAR DISEASE

For the treatment of chronic wounds and ulcers resulting from peripheral vascular disease, apply Becaplermin (X Gel) to the ulcer surface up to twice daily, or as directed by the physician.

APPLICATION IN DIAGNOSIS AND STUDY OF TISSUE RESPONSE TO INJURY

For the study of tissue response to injury, apply Becaplermin (X Gel) to the ulcer surface up to twice daily, or as directed by the physician.

Table 1: Formula to Calculate Length of Gel in Inches to Be Applied Daily

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provider if you:
- have cancer
- have poor blood flow to your lower legs and feet
- have allergies to any of the ingredients in REGRANEX.

See the end of this Medication Guide for a complete list of ingredients in REGRANEX.

- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if REGRANEX will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if REGRANEX passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you apply other medicines to diabetic ulcers of your legs or feet. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use REGRANEX?
- Use REGRANEX together with good ulcer care, as prescribed by your healthcare provider. This includes following your healthcare provider’s instructions about not putting weight on the affected leg and foot (non-weight-bearing).
- Use REGRANEX exactly as your healthcare provider tells you to use it.
- REGRANEX is for use on skin ulcers only. Do not use REGRANEX in your mouth, eyes, or vagina.
- REGRANEX comes as a gel. Your healthcare provider should tell you how often to use REGRANEX and how much REGRANEX to use.
- Your healthcare provider should check the size of your ulcer every 1 to 2 weeks.
- Your healthcare provider may change the amount of REGRANEX you apply to your ulcer as the size of your ulcer changes. So, the amount of REGRANEX to be squeezed from the tube may change as the size of your ulcer changes.
- Close your REGRANEX tube tightly after each use.
- Put the REGRANEX tube back in the refrigerator after each use.
- Use a cotton swab, tongue depressor, or other application aid when you apply your REGRANEX. Do not let the tip of your REGRANEX tube touch the ulcer or any other surface.
- Apply REGRANEX one time each day.

Apply REGRANEX as follows:
- Wash your hands well before you apply REGRANEX.
- Carefully measure the amount of REGRANEX your healthcare provider tells you to use.
- Squeeze the amount of REGRANEX needed for your ulcer on to a clean, firm, non-absorbable surface, such as wax paper.
- Use a clean cotton swab, tongue depressor, or similar application aid, to spread the REGRANEX gel in a thin layer over the surface of the ulcer on your foot or leg.
- Cover the area with a saline-moistened gauze dressing.

with saline or water to remove the rest of the REGRANEX. Cover the ulcer with a new saline moistened gauze dressing. Do not apply any more REGRANEX.

What are the possible side effects of REGRANEX?

See the section, “What is the most important information I should know about REGRANEX”.

Common side effects of REGRANEX include:
- red skin rash
- burning at the application site

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of REGRANEX. For more information, ask your doctor or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REGRANEX?
- Store REGRANEX in the refrigerator at 36°F to 4°C (2°C to 8°C).
- Do not freeze REGRANEX.
- Do not use REGRANEX after the expiration date (the bottom of the bottle).

Keep REGRANEX and all medicines out of the reach of children.

General information about REGRANEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use this Medication Guide for a condition for which it was not prescribed. Do not give REGRANEX to other people even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about REGRANEX. You should not use REGRANEX unless your healthcare provider tells you to use REGRANEX. You can ask your healthcare provider or pharmacist for information about REGRANEX that is written for healthcare professionals.

What are the ingredients in REGRANEX?

Active ingredient: bacapalamin.

Inactive ingredients: carboxymethylcellulose sodium; glycerin; methylparaben; propylparaben; sodium acetate; trihydrate; sodium chloride; water for injection.

Manufactured by: Smith & Nephew, Inc.
Fort Worth, TX 76107
U.S. Govt. License # 2004
Marketed by: Smith & Nephew, Inc.
Fort Worth, TX 76107
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Part No. 143094-0814
Revised: August 2014

This Medication Guide has been approved by the U.S. Food and Drug Administration.