An advanced therapy you can trust

Smith+Nephew

REGRANEX◊
(becaplermin) gel 0.01%

+ Engineered for **growth**

The first and only FDA-approved recombinant platelet-derived growth factor (PDGF) therapy for diabetic neuropathic ulcers.

Early use of advanced therapies like REGRANEX◊ gel is advocated by wound care experts and is an adjunct to good ulcer care.[2-3]

Simple, three-step application process makes at-home use convenient for your patients.[2]

Proven 32% faster at closing diabetic neuropathic ulcers over placebo.[1]

Easy-to-calculate dosing is convenient and makes starting patients simple.

Delivered 43% greater incidence of complete closure (100% re-epithelialization, zero exudate) with REGRANEX gel (P=0.007) vs. placebo gel[1]

Excellent formulary coverage for Medicare Part D and commercially insured patients. Copay Assistance Program available.

Important Safety Information

Indications: REGRANEX (becaplermin) gel 0.01% ("REGRANEX") is a prescription only medication indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, an not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. **Contraindications:** REGRANEX is contraindicated in patients with known neoplasm(s) at the site(s) of application. **Warnings and Precautions:** Malignancies distant from the site of application have occurred in REGRANEX users in a clinical study and in postmarketing use. REGRANEX contains becaplermin, a recombinant human platelet-derived growth factor, which promotes cellular proliferation and angiogenesis. The efficacy of REGRANEX has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. REGRANEX is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention. **Adverse Reactions:** In clinical trials, erythematous rashes occurred in 2% of subjects treated with REGRANEX (and good ulcer care) or placebo (and good ulcer care). In a retrospective follow-up study, eight of 291 subjects (2.7%) from the REGRANEX group, and two of 200 subjects (1%) from the placebo group were diagnosed with cancers during the follow-up period. An increased rate of death from systemic malignancies in patients dispensed three or more tubes of REGRANEX, observed in one of three retrospective postmarketing studies. Other adverse reactions that have been reported include a burning sensation, and erythema at the site of application. The risk information provided herein is not comprehensive. To see the complete prescribing information, please see the FDA-approved product labeling, here: https://www.smith-nephew.com/global/assets/pdf/products/wound/regranex%20label.pdf. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

References: 1. Wieman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. A phase III randomized placebo-controlled double-blind study. *Diabetes Care.* 1998;21:822-827. **2.** REGRANEX gel Prescribing Information. **3.** Kirsner RS. The standard of care for evaluation and treatment of diabetic foot ulcers. The University of Michigan Medical School. The University of Michigan Health System's Educational Services for Nursing. Barry University School of Podiatric Medicine 2010. Available at: http://www.barry.edu/includes/docs/continuing-medical-education/diabetic.pdf. Accessed July 31, 2018.

Advanced Wound Management
Smith & Nephew, Inc.
Fort Worth, TX 76109 USA
www.smith-nephew.com

1-800-876-1261
T 727-392-1261
F 727-392-6914