REGRANEX Gel in action: A case study summary

Smith+Nephew

REGRANEX◊
(becaplermin) gel 0.01%

Please see the Indications and Important Safety Information on the back.

Case study: Right great toe wound

Contributed by David M. Davidson, DPM

Patient profile:

82-year-old white male presented with large, infected wound located to the plantar aspect of the right great toe. Patient had long-standing history of idiopathic neuropathy as well as hypertension, IDDM and chronic kidney disease.

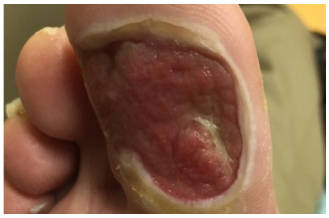
Case history:

Patient tried over-the-counter antibiotic ointment, but swelling seemed to get progressively worse. Right foot became painful, swollen, and red with purulent drainage.

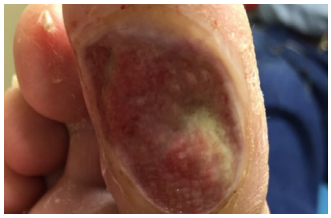
Patient then visited emergency room at local hospital. Wound measured 3cm x 2.5cm x 0.2cm at presentation. Patient had no previous treatments aside from antibiotic ointment. Patient received an angiogram to determine vascularity and underwent sharp debridement a week later.

He was discharged to home care with REGRANEX◊ (becaplermin) Gel 0.01% 3 days post-debridement with forefoot offloading wedge shoe.

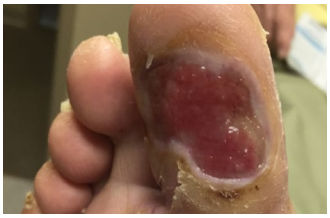
A home health nurse monitored patient's care until patient was seen by a provider 4 weeks later.



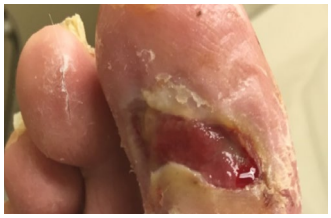
Day 1



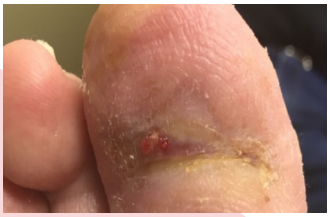
Day 7



Day 14



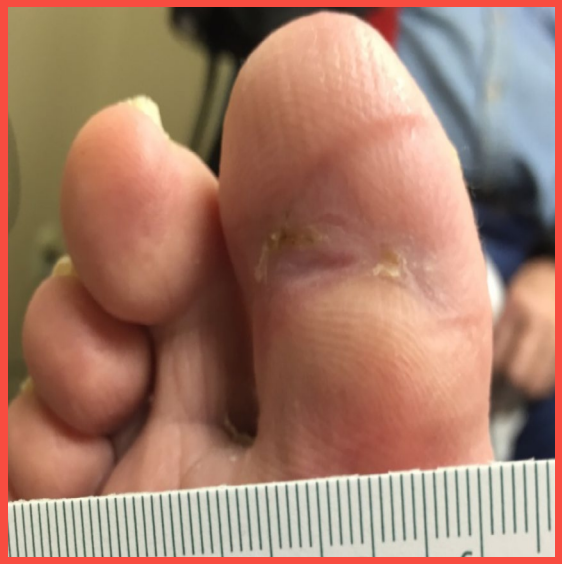
Day 34



Day 53

Treatment:

Day 07	REGRANEX Gel started and continued offloading. Ulcer measured 3cm x 2.3cm x 0.1cm
Day 14	Ulcer measured 2cm x 1.5cm x 0.1cm
Day 34	Ulcer measured 2cm x 1cm x 0.1cm
Day 53	Ulcer measured 0.2cm x 0.1cm
Day 71	Full wound closure was achieved, about 2.4 months after REGRANEX Gel and offloading were prescribed (along with initial sharp debridement).



Results: Full wound closure in 2.4 months with initial sharp debridement, REGRANEX Gel and offloading.

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

Case study: Infected left foot ulceration

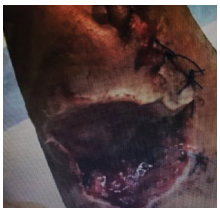
Contributed by Dr. Vincent Sollecito DPM, CWS

Patient profile:

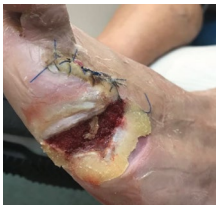
57-year-old type II diabetic admitted from the emergency room with an infected left foot ulceration, of one-day duration. He noted an ulceration after walking 18 holes of golf the day before admission. He developed fever and chills.

Case history:

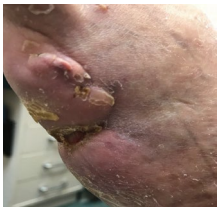
Tailor's bunion, palpable pulses, cellulitis left foot and lateral ankle. Decreased sharp sensation, decreased vibratory sensation, decreased Semmes-Weinstein sensation. Full-thickness Wagner Grade I ulceration, with necrotic capsule exposure, foul-smelling exudate over the fifth metatarsal head. Wound measured 1.5 cm x 1.5 cm x 7 mm, no granulation tissue present. Radiographs negative for osteomyelitis or gas. MRI was positive for osteomyelitis proximal phalanx fifth toe, fifth metatarsal head left foot. Arterial doppler showed triphasic waveforms, ABI greater than 1.



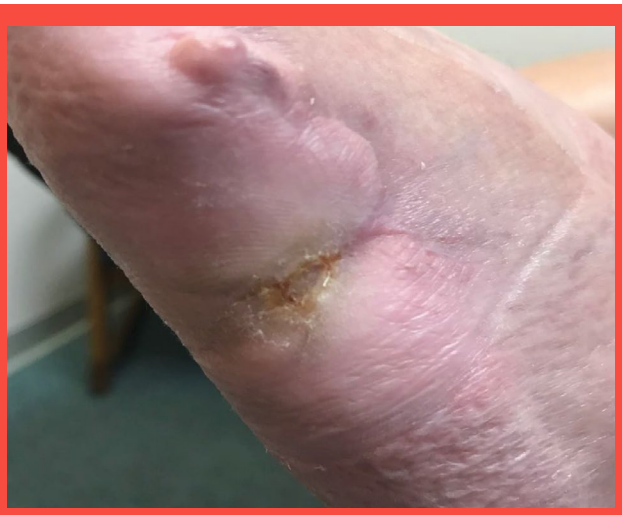
Day 01



Day 09



Day 49



63 days post-op: 63 days post-op: Wound closed with 100% epithelialization in nine weeks. Patient instructed to apply Vaseline, and cover the wound with dry gauze, changing daily for the next 30 days.

Treatment:

Day 01 - Operative state
Intraoperative findings included an infected capsule, soft bone at the fifth metatarsal head with muscle and tendon intact. Procedure was a fifth toe amputation with excision of distal one third fifth metatarsal. Wound debridement with VERSAJET◊ II Hydrosurgical system in operating room. Wound measurement was 3.5 cm x 3.5 cm x 2 cm. Two days later patient discharged from hospital, prescribed 6 weeks of IV antibiotics, NPWT change twice a week, non-weight bearing left foot using crutches and postoperative shoe.

Day 09 - post-op
Wound had 100% granulation tissue. Wound measurement was 3.5 cm x 1.5 cm x 5 mm. Wound sharp debrided. Collagen applied. REGRANEX Gel ordered to stimulate epithelialization. Patient instructed to wash wound with mild soap and water, apply REGRANEX Gel daily, cover with dry gauze, as wound was moist, and replace with saline moistened gauze at bedtime. He was to apply the collagen daily until he received the REGRANEX two days later. He was seen every other week for sharp debridement in the office.

Day 49 - post-op
Wound measurement was 5 mm x 5 mm x 1 mm. 100% red/pink granulation tissue. Peri-wound callus present. Patient referred for custom orthotics. Patient was seen every 14 days, for sharp debridement and reapplication of REGRANEX Gel. The wound was cleansed in the office with wound wash, REGRANEX applied, and covered with a collagen dressing. Patient instructed to remove the collagen the following day and resume applying REGRANEX Gel in the morning and applying saline moistened gauze in the evening. Patient to resume REGRANEX Gel application daily.

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

Case study: Diabetic neuropathic ulcer

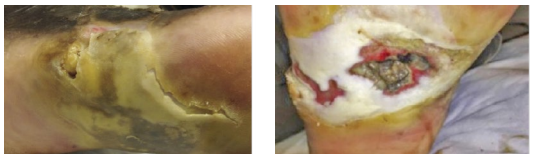
Presented by William A. Lois, MD

Patient profile:

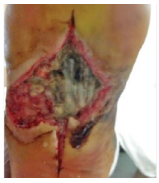
The patient is a 56-year-old African American male with a malodorous, infected ulcer on his right foot. The patient visited the physician's office and was advised by the physician that the wound had become severely infected. The patient was a noncompliant and uncontrolled diabetic.

Case history:

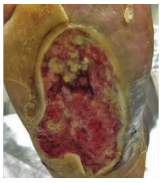
The patient presented with a full-thickness wound covering approximately 50% of the plantar surface of the right foot. The wound consisted of extensive, oozing necrotic tissue, surrounded by edema and the presence of macerated slough. An observational diagnosis of necrotizing fasciitis was made (and later confirmed by lab results). No other symptoms related to the wound were reported by the patient and no prior wound care had been performed on the foot by the patient or any health care professional.



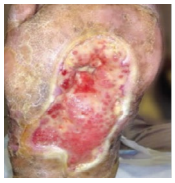
Day 1-4



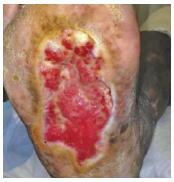
Day 04



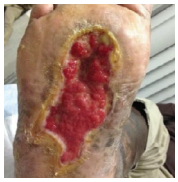
Day 28



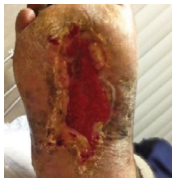
Day 43



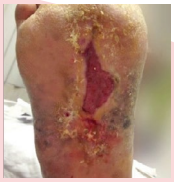
Day 52



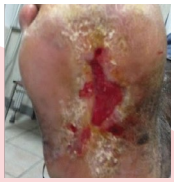
Day 64



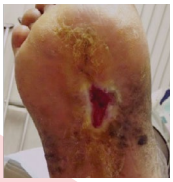
Day 85



Day 115



Day 127



Day 149

Treatment:

Day 1 Wound unroofed in physician's office. Remaining white area surrounding necrotic tissue is edema.

Day 01-04 Immediate admittance to hospital via emergency room. Placed on IV antibiotics, glycemic control implemented. Wide excisional debridement performed in operating room. Subsequent bedside debridement performed. Subcutaneous air in the plantar present confirming necrotizing fasciitis.

Day 04 Post-wide excisional and bedside debridements. Wound measures 12.0 cm x 10.0 cm. Daily application of SANTYL® Ointment initiated. Discharged from hospital on day 10. Home wound care and offloading continued.

Day 28 First office visit approximately three weeks after hospital discharge. Wound measurements not taken, appeared unchanged. 40% reduction in slough, no edema present. Granulation tissue replacing necrotic tissue. Edges pared. Daily application of SANTYL Ointment continued.

Day 43 Wound measures 11.0 cm x 6.0 cm. Healthy granulation tissue present. Reduction in slough; evidence of re-epithelialization. Daily application of SANTYL Ointment continued. Home wound care and offloading continued.

Day 52 Wound measures 10.0 cm x 6.0 cm. 75% granulation tissue present. 25% necrotic tissue present. Daily application of SANTYL Ointment continued. Home wound care and offloading continued.

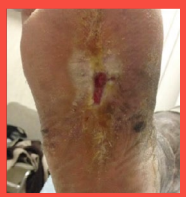
Day 64 Wound measures 10.0 cm x 5.0 cm. 100% healthy granulation tissue present. SANTYL Ointment discontinued. Daily application of REGRANEX® Gel with a moist dressing initiated.

Day 85 Wound measures 8.0 cm x 4.0 cm. Edges pared. Daily application of REGRANEX Gel continued. Home wound care and offloading continued.

Day 115 Wound measures 8.0cm x 3.0cm. Edges pared. Daily application of REGRANEX Gel continued. Home wound care and offloading continued.

Day 127 Wound measures 6.0 cm x 3.0 cm. No further sharp debridement. Daily application of REGRANEX Gel continued. Home wound care and offloading continued

Day 149 Wound measures 2.0 cm x 1.5 cm. Daily application of REGRANEX Gel continued. Home wound care and offloading continued.



Day 172 Wound measures 1.5 cm x 0.8 cm. Patient ran out of REGRANEX Gel following this visit. Treatment switched to hydrogel and moist dressing only. Patient did not return for final visit; informed physician of total wound closure via telephone call.

Results: Enzymatic debridement with SANTYL Ointment for 61 days, followed by approximately 109 days of REGRANEX Gel, resulted in the complete closure of this highly complex wound.

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

Case study: Left foot chronic Wagner Grade 3 ulceration

Contributed by Bradford M. Fine, MS, DPM, FACFAS, PLLC

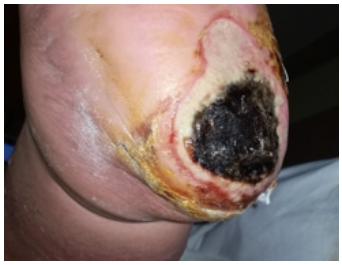
Patient profile:

55-year old white male was referred to wound care center for a blister on his heel. He was treated with oral antibiotics, ovidone-iodine and dry sterile dressing. Two weeks later, patient went to ER with infected DFU (8cm x 8cm x 2cm plantar posterior). He was admitted by a hospitalist and consulted a podiatrist. Patient was presented with long list of comorbidities (diabetes, anemia of chronic disease, cellulitis, chronic acquired lymphedema, chronic renal disease, arterial hypertension, polyostotic osteomyelitis).

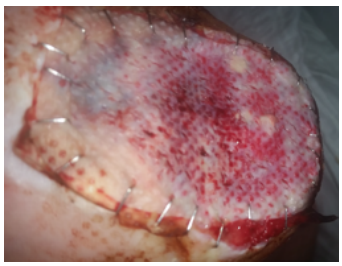
Case history:

X-ray revealed ankyloses of tarso-metatarsal joints and large plantar spur. Patient had prominent soft tissue swelling over the dorsum of the foot measuring approximately 3.0cm in thickness. An MRI revealed polyostotic osteomyelitis. Ulcer was debrided to subcutaneous tissue and patient was fit with antimicrobial heel foam dressing.

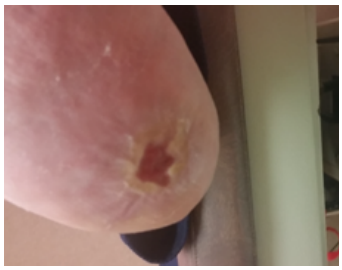
Day 01



Day 11



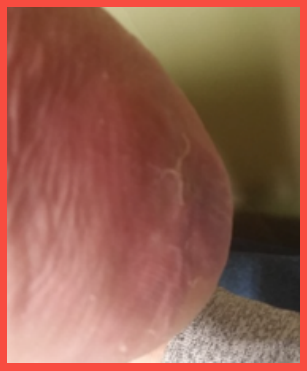
Day 127



Treatment:

Day 01	Ulcer was debrided to subcutaneous tissue and patient was fit with antimicrobial heel foam dressing.
Day 06	Patient received surgical debridement and split-thickness graft.
Day 08	Ulcer measured 6cm x 8cm x 1.5cm. Negative pressure wound therapy (NPWT) began with post-op window pane NPWT to arch with non-adherent dressing. Patient sent to continuing care.
Day 11	Ulcer measured 7cm x 4cm x 0.5cm. NPWT continued, including NPWT bridge to arch with non-adherent dressing.
Day 36	Graft staples were removed. Ulcer measured 5cm x 4cm x 0.3cm; wound began to grow larger.
Day 46	Ulcer measured 5cm x 5.5cm x 0.3cm. NPWT was discontinued, and patient started on REGRANEX (becaplermin) Gel 0.01% in conjunction with sharp debridement, non-adherent dressing and dry sterile dressing.
Day 46-127	Ulcer measured 2.0cm x 1.9cm x 0.2cm. REGRANEX Gel therapy continued.
Day 134	Ulcer measured 0.3 x 0.4 x 0.3

Day 148



Results: After patient was presented at ER with DFU measuring 8cm x 8 cm x 2cm, wound closed by 99% after 81 days of treatment with REGRANEX Gel and sharp debridement. Wound resolved after **148 days of total treatment, including 102 days of REGRANEX Gel use.**

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

Case study: Complex foot wound

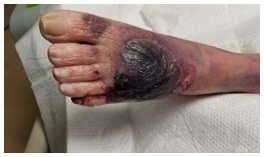
Presented by Dr. Bradford M. Fine MS, DPM, PLLC, FACFAS

Patient profile:

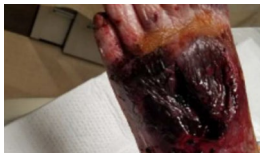
60-year-old male patient with non-healing left foot wound complicated by uncontrolled diabetes mellitus, type 2. Patient dropped something on the dorsum on the left foot. Patient was on blood thinners. A large, blood-filled bullae formed and opened spontaneously. Patient reported no treatment prior to assessment and was trying to allow the wound to heal on its own. Wound enlarged and did not heal.

Case history:

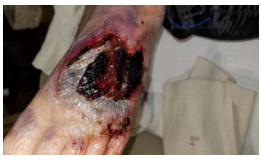
Patient admitted to hospital for sepsis, lactic acidosis, leukocytosis, hypotension, cellulitis of left lower extremity, acute renal failure, COPD, diarrhea, elevated liver panels secondary to sepsis, metabolic acidosis, anemia. Other medical history includes CAD, GERD, and hypothyroidism. Had taken IV antibiotics, including vancomycin, flagyl, and tigecyline. Wound measurements were 8 cm x 6 cm x 0.3 cm at first presentation with minimal drainage. The comorbidity of type II diabetes is a limiting factor preventing the ability to heal the traumatic wound along the acute healing trajectory.



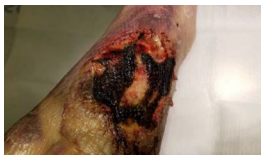
Assessment



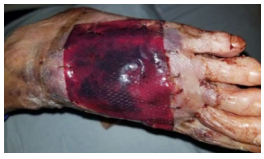
Day 01



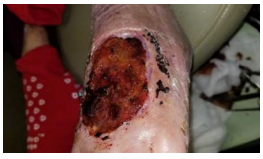
Day 03



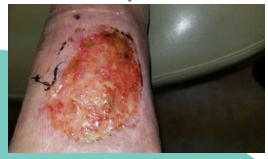
Day 08



Day 08



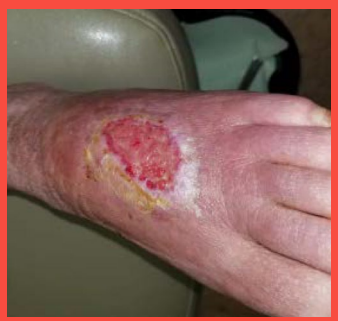
Day 37

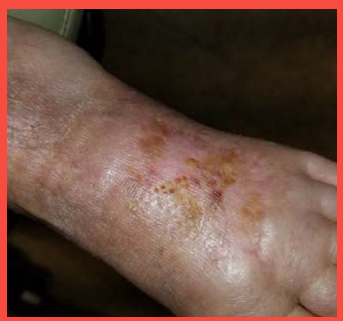


Day 51

Treatment:

Day 01	Sharp debridement. Initial incision and drainage at bedside. Started saline moist dressings with non-adherent layer and dry sterile gauze daily.
Day 03	Dressing changed at bedside. Wound measurement was 7 cm x 5.5 cm x 0.2 cm. Continued treatment plan of saline moist dressings with non-adherent layer and dry sterile gauze daily.
Day 08	Re-evaluation of the food wound. Wound had a small amount of pink tissue. Wound size was unchanged. Necrotic tissue present. Planned sharp debride and placement of Integra over wound.
Day 08 Graft placement	Wound sharp debrided and Integra placed. Dressing changes every 3 days using ACTICOAT®, gauze 4x4s, gauze wrap and elastic self-adherent wrap. Discharged for hospital 2 weeks later.
Day 37	Wound bed characteristic of Integra. Wound measurement was 6 cm x 5 cm x 0.1 cm. Scheduled a sharp debridement and placement of allograft (placed on day 45).
Day 51	Wound bed with some granulation but still remained largely fibrotic in nature. Wound measurement 5 cm x 3.5 cm x 0.1 cm. Collagenase SANTYL® Ointment 250 units/g initiated.
Day 95	Wound has decreased in size but not closed completely. Wound bed was red/pink and measures 3cm x 2 cm x 0.1 cm. Initiation of REGRANEX Gel daily with saline moist non-adherent dressing. Every 1-2 weeks follow-up for sharp debridement in office.





Results: Six months from initial injury the wound is completely closed. Foot was being monitored for recurrence of wound.

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

A front-line solution to a serious problem[1]

Manageable at-home application

A convenient 3-step application process for your patients[1]

1. Prepare

- Wash hands
- Squeeze the calculated length of REGRANEX◊ Gel on a clean, firm, non-absorbent surface, such as wax paper

2. Apply

- Use application aid to spread REGRANEX Gel in a thin, even layer of approximately 1/16-inch thickness over the entire ulcer area
- Thickness of gel to be applied is about the thickness of a penny

3. Cover

- Cover area with saline-moistened gauze dressing
- After approximately twelve hours, gently remove the dressing and rinse ulcer with saline or water to remove remaining REGRANEX Gel
- Cover ulcer with new saline-moistened dressing (without REGRANEX Gel) for the remainder of the day

DO NOT let the tip of the REGRANEX Gel tube touch the ulcer or any other surface.

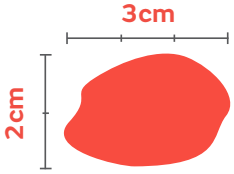
REMIND patients to refrigerate REGRANEX Gel

Straightforward dosing

Easy-to-calculate measurements for REGRANEX◊ (becaplermin) Gel, 0.01%

The dosing calculation:[1]

ulcer length (cm) x ulcer width (cm) ÷ 4 = **length of gel to be applied (cm)**



Sample calculation for 3cm x 2cm ulcer:

3cm x **2cm** ÷ **4** = **1.5cm** → **Apply 1.5 cm of REGRANEX Gel**

3cm: ulcer length; 2cm: ulcer width; 1.5cm: gel application

Note: Individual results will vary. For this case study, REGRANEX Gel was applied in conjunction with proper ulcer care. The information listed herein does not constitute the complete history of treatment for this wound. Ask your Smith+Nephew representative for more detailed information about this case study.

Important Safety Information

Indications:

REGRANEX (becaplermin) Gel 0.01% ("REGRANEX") 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, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.

Contraindications:

REGRANEX Gel 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 Gel users in a clinical study and in postmarketing use. REGRANEX Gel contains becaplermin, a recombinant human platelet-derived growth factor, which promotes cellular proliferation and angiogenesis. The efficacy of REGRANEX Gel 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 Gel 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 Gel (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 Gel 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 Gel, 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

References: 1. REGRANEX° Gel Prescribing Information. **2.** Lantis JC II, Boone D, Gendics C, Todd G. Analysis of patient cost for recombinant human platelet-derived growth factor therapy as the first-line treatment of the insured patient with a diabetic foot ulcer. Adv Skin Wound Care. 2009;22:167-171. **3.** Data on file. Smith & Nephew. October 2012.

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

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