

Case study: Diabetic neuropathic ulcer

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Smith+Nephew

Collagenase
SANTYL [◇]
Ointment 250 units/gram

REGRANEX [◇]
(becaplermin) gel 0.01%

Patient

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.

Wound presentation

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.

Treatment

The unroofing of necrotic tissue was performed in the physician's office. The patient was immediately admitted to the hospital via the emergency room for further intervention. Treatment included: initiating IV antibiotics, performing a wide excisional debridement in the operating room and a bedside sharp debridement. SANTYL Ointment was initiated for enzymatic debridement for a period of time, followed by REGRANEX gel. The patient had ongoing office visits and sharp debridements in the form of paring of the wound edges, throughout the case. The patient was also referred to an endocrinologist for glycemic control. The patient was compliant with all home wound care and maintaining controlled glycemic levels.

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.

Individual results may vary.

Treatment

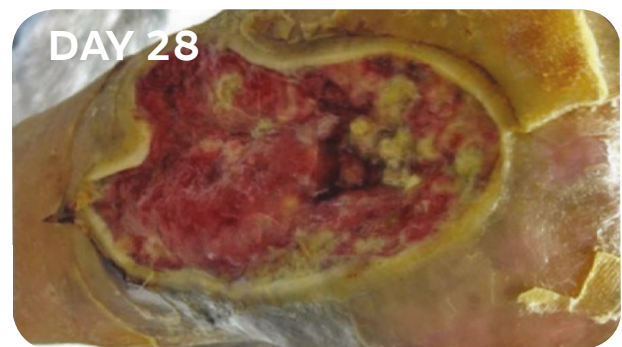


Days 1-4

- Wound unroofed in physician's office
- Remaining white area surrounding necrotic tissue is edema
- Macerated slough present 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
- Blood glucose level confirmed polymicrobial dominant strain



- Post-wide excisional and bedside debridements
- Wound measures 12.0cm x 10.0cm
- Daily application of SANTYL[®] Ointment initiated
- Discharged from hospital on day 10
- Instructed to maintain glycemic control
- Home wound care and offloading continued



- 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
- Home wound care and offloading continued

Treatment



- Wound measures 11.0cm x 6.0cm
- Healthy granulation tissue present
- Reduction in slough; evidence of re-epithelialization
- Edges pared
- Daily application of SANTYL[®] Ointment continued
- Home wound care and offloading continued



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



- Wound measures 10.0cm x 5.0cm
- 100% healthy granulation tissue present
- SANTYL Ointment discontinued
- Edges pared
- Daily application of REGRANEX[®] (becaplermin) gel, 0.01% with a moist dressing initiated
- Home wound care and offloading continued

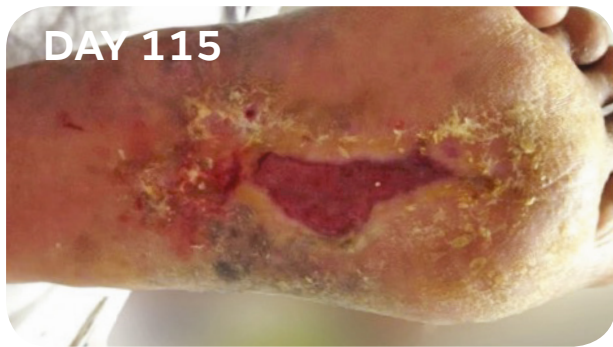


- Wound measures 8.0cm x 4.0cm
- Edges pared
- Daily application of REGRANEX gel continued
- Home wound care and offloading continued

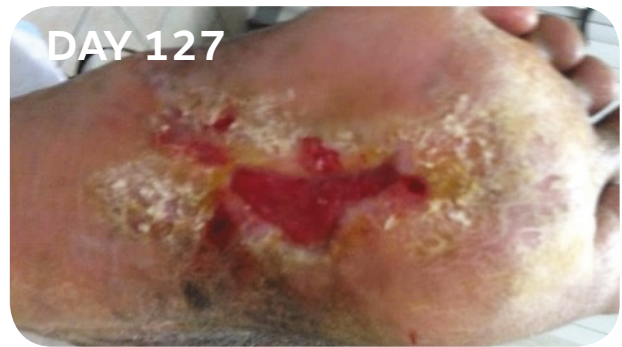


Learn more

Treatment



- Wound measures 8.0cm x 3.0cm
- Edges pared
- Daily application of REGRANEX[®] (becaplermin) gel, 0.01% continued
- Home wound care and offloading continued



- Wound measures 6.0cm x 3.0cm
- No further sharp debridement
- Daily application of REGRANEX gel continued
- Home wound care and offloading continued



- Wound measures 2.0cm x 1.5cm
- Daily application of REGRANEX gel continued
- Home wound care and offloading continued



- Wound measures 1.5cm x 0.8cm
- 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

Important Safety Information

Indications: Collagenase SANTYL Ointment ("SANTYL") is a prescription-only medication indicated for debriding chronic dermal ulcers and severely burned areas. **Contraindications:** SANTYL is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. **Warning and Precautions:** The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme's activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. As such, the wound should be properly cleansed prior to application of SANTYL. Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when SANTYL was not confined to the wound. SANTYL is not indicated for wound closure. Discontinue use of SANTYL after granulation tissue is well-established. **Adverse Reactions:** No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. The risk information provided herein is not comprehensive. For complete prescribing information, please refer to the accompanying PI or visit: <https://santyl.com/sites/default/files/2019-12/SANTYL-PI.pdf>. You are encouraged to report negative side effects of prescription drugs to FDA. Visit MedWatch or call 1-800-FDA-1088.

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, and 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. For complete prescribing information, please refer to the accompanying PI or visit: https://regranex.com/pdf/PI_Full_Version.pdf. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.