

**VENELEX™ OINTMENT**  
Wound Dressing  
(Balsam Peru and Castor Oil USP)

**Rx Only**

**DESCRIPTION:** VENELEX™ OINTMENT contains Balsam Peru, Castor Oil USP, Glyceryl Monostearate and White Petrolatum.

**ACTION:** VENELEX™ OINTMENT helps to deodorize and protectively cover pressure wounds (ulcers) and may help with the reduction of pain. VENELEX™ OINTMENT provides a moist wound environment conducive to healing. The moisturizing properties of VENELEX™ OINTMENT also help in the prevention of cracking around the edges of sores.

**INDICATIONS:** VENELEX™ OINTMENT is a wound dressing for topical use in the management of chronic and acute wounds, and dermal ulcers including: pressure ulcers (Stage I-IV), venous stasis ulcers, diabetic ulcers, first and second degree burns, surgical wounds, traumatic wounds, superficial wounds, ulcers resulting from arterial insufficiency and grafted wound/donor sites.

**CONTRAINDICATIONS:** VENELEX™ OINTMENT is contraindicated in persons who have shown hypersensitivity to Balsam Peru, Petrolatum or any of the other ingredients used in this ointment.

**USES:** VENELEX™ OINTMENT is easy to apply and quickly reduces odors frequently accompanying a decubitus ulcer. The wound may be left open or appropriate dressing applied. Please note that wounds generally heal poorly in the presence of hemoglobin or zinc deficiency.

**WARNING: FOR EXTERNAL USE ONLY.** Do not apply to fresh arterial clots. Avoid contact with eyes. Keep this and all other medications out of reach of children. Keep tightly closed. Use only as directed by a physician. When applied to a sensitive area, a temporary stinging may occur.

**USUAL DOSAGE:** Apply a thin film of VENELEX™ OINTMENT topically a minimum of twice daily or as often as necessary. Wound may be left unbandaged or appropriate dressing can be applied. To remove, wash gently with an appropriate wound cleanser.

**HOW SUPPLIED:** VENELEX™ OINTMENT is supplied as follows:

SIZE	NDC NUMBER
30 GRAM TUBE	58980-780-11
60 GRAM TUBE	58980-780-21
5 GRAM PACKETTE X 60	58980-780-50

**STORAGE:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. [See USP Controlled Room Temperature]. Protect from freezing. See crimp for lot number and expiration date.

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Customer Service  
Telephone: 1-800-442-7882 | Fax: 305-254-6875  
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**Provides an environment  
that supports  
wound  
healing.**



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*Celebrating 30 years in Wound care*

# VENELEX™ OINTMENT

## Wound Dressing

(Balsam Peru and Castor Oil USP)

### A Comparison of Balsam Peru Ointment with and without Trypsin in the Healing of Chronic Dermal Ulcers.

Marc A. Berkowitz DPM, Jacqueline K. Donovan MS-III

**Introduction:** This is a study in which the clinical performance of Balsam Peru Ointment (Venelex)<sup>1</sup> and a commercially available Trypsin Balsam Peru Ointment (Xenaderm)<sup>2</sup> are evaluated in a group of ten (10) subjects each (total of twenty (20) patients) with chronic dermal ulcers of longer than 3 months in duration that have not responded to standard of care. Both products are of similar formulation with the exception of the Trypsin component.

*Balsam Peru Ointment without Trypsin has been subjected to cytotoxicity testing, irritation potential and sensitization studies as required by the USFDA and found to be safe.*

**Methods:** This open label, randomized, parallel comparison study examined outcomes from treatment of foot ulcers of various etiologies with Trypsin Balsam Peru Ointment and Balsam Peru Ointment without Trypsin in conjunction with a high moisture vapor transmission rate dressing.

Wound areas were measured using acetate tracings of the wound perimeter on day 0, then weighed on an analytical balance and converted to square centimeter area via a conversion factor generated from the weight of a known area of the acetate sheet (grams/square centimeter). Day 0 wound areas were not significantly different. Wounds enrolled in the Trypsin Balsam Peru group averaged 4.0 square centimeters and wounds enrolled in the Balsam Peru Ointment without Trypsin averaged 3.52 square centimeters. Further, each wound was photographed on day 0, at each interim evaluation and upon wound closure. All wounds were treated and dressed with secondary dressings which constituted the test facilities standard of care.

**Results:** Epithelialization and wound closure was achieved in a total of 55 days for Balsam Peru Ointment (10 patients) and a total of 57 days for Balsam Peru Ointment with Trypsin (10 patients). All twenty cases successfully healed to complete closure and showed no signs of infection during the study.

**Conclusions:** In conclusion, the two products demonstrated no significant difference in the acceleration of wound healing. Balsam Peru Ointment without Trypsin appears to provide a comparable efficacy to Balsam Peru Ointment with Trypsin in accelerating healing in dermal wounds.

**Comments:** The purpose of this study was to determine whether Balsam Peru Ointment with and without Trypsin, in conjunction with a high MTRV dressing would accelerate healing in dermal wounds. Both ointment formulations were found to be equally effective in promoting granulation tissue. The development of healthy granulation tissue as well as the rate of wound area reduction over time did not show any significant difference between the two products. The quality of granulation tissue was evaluated based on the presence of adequate perfusion, minimal growth of pathologic tissue and epidermal migration across the wound bed.

Evidence of epithelialization correlated with the development of a granulating wound bed as determined by visual assessment. The establishment of healthy granulation tissue demonstrates the achievement of optimal moisture regulation of the wound bed. In the opinion of this investigator, for optimal wound healing, a controlled balance of moisture in the wound bed promotes the establishment of healthy granulation tissue. The proper control of infection, pathologic tissue, debridement and treatment of the underlying etiology of the ulcer promotes wound closure. This evaluation suggests that the role of the non-specific protease, Trypsin, in healing chronic diabetic ulcers in humans, is in question. Trypsin in Balsam Peru Ointment is not approved for use in human wounds in the USA.

1. Venelex (Venelex is a registered trademark of Stratus Pharmaceuticals Inc.)
2. Xenaderm (Xenaderm is a registered trademark of Healthpoint, Ltd)
3. Study conducted at UH Bedford Medical Center, Wound Care Department, Bedford, OH 44146



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