
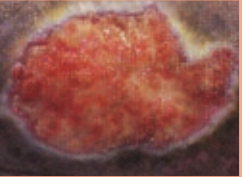


# Enzymatic Debridement With Collagenase SANTYL® Ointment

	Pressure Ulcer Stage 4–Knee	Pressure Ulcer Unstageable–Hip	Diabetic Foot Ulcer	Burn	Non-progressing Venous Leg Ulcer
					
<b>Description</b>	Partial to full thickness wound with slough/fibrin	Wound with eschar/dried necrosis	Full thickness wound with slough; signs of surgical removal of callus on margins	Deep, partial thickness burn with white eschar	Non-progressing wound
<b>Drainage</b>	Minimal to heavy	None	Low to moderate	Minimal to heavy	None to heavy
<b>Clinical Action</b>	Active, selective debridement	Active, selective debridement	Active, selective debridement	Active, selective debridement	Active, selective debridement
<b>Treatment Goal</b>	Clean, granulating wound bed	Clean, granulating wound bed	Clean, granulating wound bed	Clean burn without necrotic tissue	Progression

Not intended to supersede independent clinical judgment or institutional protocols.

Collagenase SANTYL® Ointment is indicated for debriding chronic dermal ulcers and severely burned areas.

Occasional slight transient erythema has been noted in surrounding tissue when applied outside the wound. One case of systemic hypersensitivity has been reported after 1 year of treatment with collagenase and cortisone. Use of Collagenase SANTYL® Ointment should be terminated when debridement is complete and granulation tissue is well established.

**Please see accompanying complete prescribing information for more details.**



**Collagenase**  
**Santyl®**  
Ointment 250 units/g

Enzymatically Active • Biologically Selective

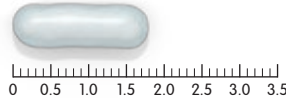
# Measurement and Application Protocol for Collagenase SANTYL® Ointment

The images below are provided as a reference and are not intended to supersede independent clinical judgment or institutional protocols.

**30-g tube:** 3.04 cm (1.20 in) = approximately 1 g<sup>1</sup>



**90-g tube:** 1.78 cm (0.70 in) = approximately 1 g<sup>1</sup>

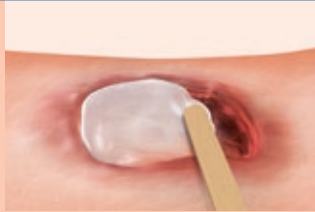


## 1 CLEANSE



- » Remove as much loose debris from the wound as possible
- » Gently cleanse the wound bed with sterile saline or an appropriate wound cleanser (optimal pH 6–8) followed by saline, each time a dressing is changed
- » When necessary, crosshatch thick eschar with a #10 blade to ensure optimal surface contact

## 2 APPLY



- » Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured
- » Apply SANTYL® Ointment at 2 mm thickness (approximately nickel thickness)
- » Apply SANTYL® Ointment within the area of the wound
- » Apply once daily (or more frequently if the dressing becomes soiled, as from incontinence)

## 3 COVER



- » Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture
- » Do not use dressings containing silver (Ag) or iodine (I<sub>2</sub>) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment

### If infection develops:

- » You may apply a topical antibiotic powder before applying SANTYL® Ointment
- » If infection persists, discontinue use of SANTYL® Ointment until the infection is resolved



Reference: 1. Data on file. Smith & Nephew, Inc., 2014.

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Collagenase  
**Santyl**  
Ointment 250 units/g

**DESCRIPTION:** Collagenase SANTYL<sup>®</sup> Ointment is a sterile enzymatic debriding ointment which contains 250 collagenase units per gram of white petrolatum USP. The enzyme collagenase is derived from the fermentation by *Clostridium histolyticum*. It possesses the unique ability to digest collagen in necrotic tissue.

**CLINICAL PHARMACOLOGY:** Since collagen accounts for 75% of the dry weight of skin tissue, the ability of collagenase to digest collagen in the physiological pH and temperature range makes it particularly effective in the removal of detritus.<sup>1</sup> Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelization of dermal ulcers and severely burned areas.<sup>2, 3, 4, 5, 6</sup> Collagen in healthy tissue or in newly formed granulation tissue is not attacked.<sup>2, 3, 4, 5, 6, 7, 8</sup> There is no information available on collagenase absorption through skin or its concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier.

**INDICATIONS AND USAGE:** Collagenase SANTYL<sup>®</sup> Ointment is indicated for debriding chronic dermal ulcers<sup>2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18</sup> and severely burned areas.<sup>3, 4, 5, 7, 16, 19, 20, 21</sup>

**CONTRAINDICATIONS:** Collagenase SANTYL<sup>®</sup> Ointment is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase.

**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. When it is suspected such materials have been used, the site should be carefully cleansed by repeated washings with normal saline before Collagenase SANTYL<sup>®</sup> Ointment is applied. Soaks containing metal ions or acidic solutions should be avoided because of the metal ion and low pH. Cleansing materials such as Dakin's solution and normal saline are compatible with Collagenase SANTYL<sup>®</sup> Ointment.

Debilated 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 Collagenase SANTYL<sup>®</sup> Ointment was not confined to the wound. Therefore, the ointment should be applied carefully within the area of the wound. Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS:** No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. However, one case of systemic manifestations of hypersensitivity to collagenase in a patient treated for more than one year with a combination of collagenase and cortisone has been reported.

**OVERDOSAGE:** No systemic or local reaction attributed to overdose has been observed in clinical investigations and clinical use. If deemed necessary the enzyme may be inactivated by washing the area with povidone iodine.

**DOSAGE AND ADMINISTRATION:** Collagenase SANTYL<sup>®</sup> Ointment should be applied once daily (or more frequently if the dressing becomes soiled, as from incontinence). When clinically indicated, crosshatching thick eschar with a #10 blade allows Collagenase SANTYL<sup>®</sup> Ointment more surface contact with necrotic debris. It is also desirable to remove, with forceps and scissors, as much loosened detritus as can be done readily. Use Collagenase SANTYL<sup>®</sup> Ointment in the following manner:

1 – Prior to application the wound should be cleansed of debris and digested material by gently rubbing with a gauze pad saturated with normal saline solution, or with the desired cleansing agent compatible with Collagenase SANTYL<sup>®</sup> Ointment (See **PRECAUTIONS**), followed by a normal saline solution rinse.

2 – Whenever infection is present, it is desirable to use an appropriate topical antibiotic powder. The antibiotic should be applied to the wound prior to the application of Collagenase SANTYL<sup>®</sup> Ointment. Should the infection not respond, therapy with Collagenase SANTYL<sup>®</sup> Ointment should be discontinued until remission of the infection.

3 – Collagenase SANTYL<sup>®</sup> Ointment may be applied directly to the wound or to a sterile gauze pad which is then applied to the wound and properly secured.

4 – Use of Collagenase SANTYL<sup>®</sup> Ointment should be terminated when debridement of necrotic tissue is complete and granulation tissue is well established.

**HOW SUPPLIED:** Collagenase SANTYL<sup>®</sup> Ointment contains 250 units of collagenase enzyme per gram of white petrolatum USP.

Do not store above 25°C (77°F). Sterility guaranteed until tube is opened.

Collagenase SANTYL<sup>®</sup> Ointment is available in 15 gram, 30 gram, and 90 gram tubes.

**REFERENCES:** 1. Mandl, I., Adv Enzymol. 23:163, 1961. 2. Boxer, A.M., Gottesman, N., Bernstein, H., & Mandl, I., Geriatrics. 24:75, 1969. 3. Mazurek, I., Med. Welt. 22:150, 1971. 4. Zimmerman, W.E., in "Collagenase," Mandl, I., ed., Gordon & Breach, Science Publishers, New York, 1971, p. 131, p. 185. 5. Vetra, H., & Whittaker, D., Geriatrics. 30:53, 1975. 6. Rao, D.B., Sane, P.G., & Georgiev, E.L., J. Am. Geriatrics Soc. 23:22, 1975. 7. Vrabec, R., Moserova, J., Konickova, Z., Behouunkova, E., & Blaha, J., J. Hyg. Epidemiol. Microbiol. Immunol. 18:496, 1974. 8. Lippmann, H.I., Arch. Phys. Med. Rehabil. 54:588, 1973. 9. German, F. M., in "Collagenase," Mandl, I., ed., Gordon & Breach, Science Publishers, New York, 1971, p. 165. 10. Haimovici, H. & Strauch, B., in "Collagenase," Mandl, I., ed., Gordon & Breach, Science Publishers, New York, 1971, p. 177. 11. Lee, L.K., & Ambrus, J. L., Geriatrics. 30:91, 1975. 12. Locke, R.K., & Heifitz, N.M., J. Am. Pod. Assoc. 65:242, 1975. 13. Varma, A.O., Bugatch, E., & German, F.M., Surg. Gynecol. Obstet. 136:281, 1973. 14. Barrett, D., Jr., & Klibanski, A., Am. J. Nurs. 73:849, 1973. 15. Bardfeld, L.A., J. Pod. Ed. 1:41, 1970. 16. Blum, G., Schweiz. Rundschau Med Praxis. 62:820, 1973. Abstr. in Dermatology Digest, Feb. 1974, p. 36. 17. Zaruba, F., Lettl, A., Brozkova, L., Skrdlantova, H., & Krs, V., J. Hyg. Epidemiol. Microbiol. Immunol. 18:499, 1974. 18. Altman, M.I., Goldstein, L., & Horwitz, S., J. Am. Pod. Assoc. 68:11, 1978. 19. Rehn, V.J., Med. Klin. 58:799, 1963. 20. Krauss, H., Koslowski, L., & Zimmermann, W.E., Langenbecks Arch. Klin. Chir. 303:23, 1963. 21. Gruenagel, H.H., Med. Klin. 58:442, 1963.

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