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Collagenase SANTYL® Ointment 250 units/g Clinical Competency for Home Healthcare Providers

Trainee Version

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PDQWC™
Professionals Dedicated to Quality Wound Care

The Collagenase SANTYL® Ointment Clinical Competency for Home Healthcare Providers was developed with input from the Professionals Dedicated to Quality Wound Care.

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Introduction

This clinical competency booklet has been developed for home healthcare providers who use or prescribe Collagenase SANTYL® Ointment. The target audience for this Collagenase SANTYL® Ointment competency includes:

- Licensed Nurses (RNs, LPNs)
- Physical Therapists
- Physician's Assistants
- Nurse Practitioners
- Physicians

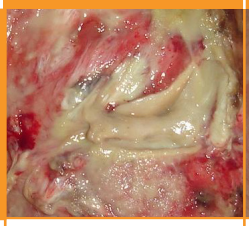
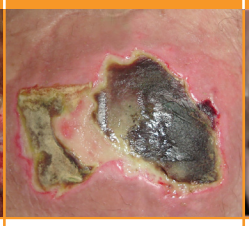
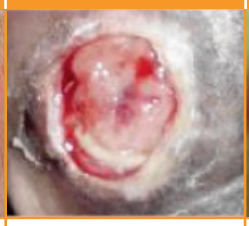
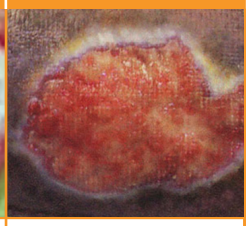
Objectives

- Distinguish the indications for Collagenase SANTYL® Ointment in debridement
- Explain the mechanism of action of Collagenase SANTYL® Ointment
- Review the appropriate amount of Collagenase SANTYL® Ointment per application
- Demonstrate proper application for Collagenase SANTYL® Ointment
- Demonstrate proper clinical practice when administering Collagenase SANTYL® Ointment

Not intended to supersede independent clinical judgment or institutional/agency protocol.

Enzymatic Debridement with Collagenase SANTYL® Ointment

Collagenase SANTYL® Ointment is the only FDA-approved enzymatic debrider. SANTYL® Ointment is indicated for debriding chronic dermal ulcers and severely burned areas.

	Pressure Ulcer Stage 4-Knee	Pressure Ulcer Unstageable-Hip	Diabetic Foot Ulcer	Burn	Non-progressing Venous Leg Ulcer
					
Description	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
Drainage	Minimal to heavy	None	Low to moderate	Minimal to heavy	None to heavy
Clinical Action	Active, selective debridement	Active, selective debridement	Active, selective debridement	Active, selective debridement	Active, selective debridement
Treatment Goal	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/agency protocol.

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.

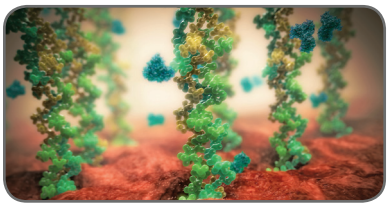
Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical posiblity that debriding enzymes may increase the risk of bacteremia.

What is Collagenase SANTYL® Ointment?

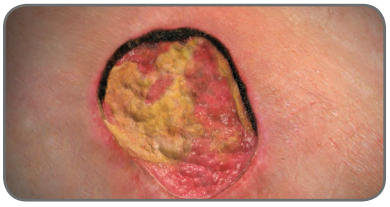
Collagenase SANTYL® Ointment 250 units/g clears the way for healthy tissue

SANTYL® Ointment is a licensed biologic and the only FDA-approved enzymatic debrider.

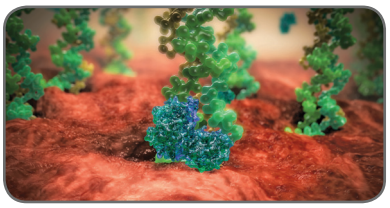
Actively and selectively remove necrotic tissue without harming granulation tissue



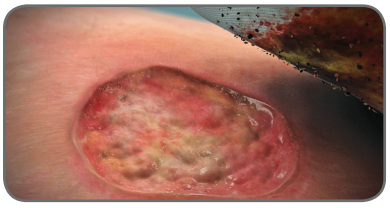
In an untreated wound, strands of collagen anchor necrotic tissue to the wound bed.



SANTYL® Ointment penetrates the wound surface by migrating through the edges of the wound and between pockets of slough, eschar, and dead tissue.



SANTYL® Ointment selectively attacks this collagen and cleaves the fiber at its attachment point. This detaches the fiber from the wound bed and frees the wound of necrotic debris.



After SANTYL® Ointment cleaves and degrades the fiber, the necrotic debris can be successfully removed through subsequent cleansing and dressing changes.

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.

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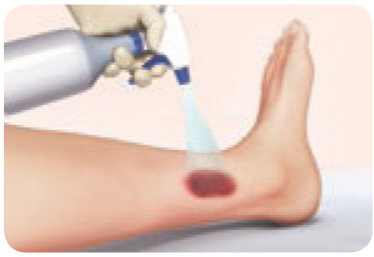
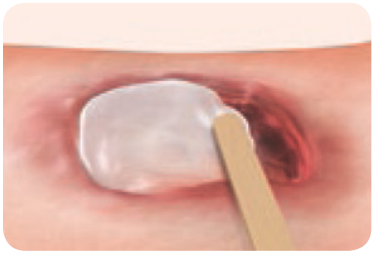
Application Process for Collagenase SANTYL® Ointment

1 CLEANSE

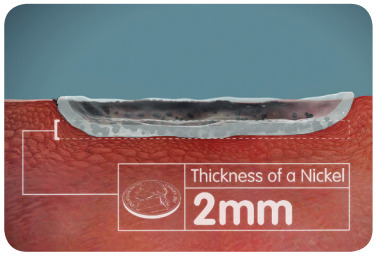


- Remove as much loose debris from the wound as possible
- Gently cleanse the wound bed with sterile saline or an appropriate wound cleanser (optimal pH 6-8) followed by saline, each time a dressing is changed
- When necessary, have a ***properly licensed clinician*** crosshatch thick eschar with a #10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

2 APPLY



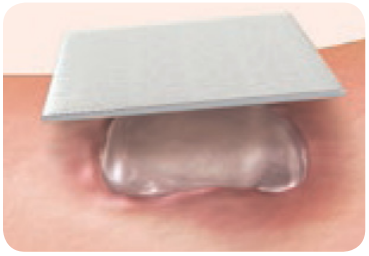
- Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured
- Apply SANTYL® Ointment at 2 mm thickness (approximately nickel thickness)
- Apply SANTYL® Ointment within the area of the wound
- Apply once daily (or more frequently if the dressing becomes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



Use the appropriate amount of ointment

- Three clinical trials found Collagenase SANTYL® Ointment to be efficacious when applied at nickel thickness (2 mm)[1-3]

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_2) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment

Considerations in case an 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

Collagenase SANTYL® Ointment Estimated Amount Per Application

30-g tube: Length (cm) of SANTYL® Ointment line per application based on wound dimensions

cm x cm	1 cm	2 cm	3 cm	4 cm	5 cm	6 cm	7 cm	8 cm
1 cm	0.5 cm	1.0 cm	1.6 cm	2.1 cm	2.6 cm	3.1 cm	3.6 cm	4.1 cm
2 cm	1.0 cm	2.1 cm	3.1 cm	4.1 cm	5.2 cm	6.2 cm	7.2 cm	8.3 cm
3 cm	1.6 cm	3.1 cm	4.7 cm	6.2 cm	7.8 cm	9.3 cm	10.9 cm	12.4 cm
4 cm	2.1 cm	4.1 cm	6.2 cm	8.3 cm	10.3 cm	12.4 cm	14.5 cm	16.5 cm
5 cm	2.6 cm	5.2 cm	7.8 cm	10.3 cm	12.9 cm	15.5 cm	18.1 cm	20.7 cm
6 cm	3.1 cm	6.2 cm	9.3 cm	12.4 cm	15.5 cm	18.6 cm	21.7 cm	24.8 cm
7 cm	3.6 cm	7.2 cm	10.9 cm	14.5 cm	18.1 cm	21.7 cm	25.3 cm	28.9 cm
8 cm	4.1 cm	8.3 cm	12.4 cm	16.5 cm	20.7 cm	24.8 cm	28.9 cm	33.1 cm

30-g tube:

3.04 cm (1.20 in) = approximately 1 g

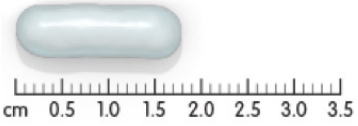
Formula: Estimated length of SANTYL® Ointment ("SO") needed from 30-g tube
= Wound area x nickel depth x SO density x approx. length of 1 g of SO
= (X cm2) x (0.2 cm) x (0.85 g/cm^3) x (3.04 cm/g)

90-g tube: Length (cm) of SANTYL® Ointment line per application based on wound dimensions

cm x cm	1 cm	2 cm	3 cm	4 cm	5 cm	6 cm	7 cm	8 cm
1 cm	0.3 cm	0.6 cm	0.9 cm	1.2 cm	1.5 cm	1.8 cm	2.1 cm	2.4 cm
2 cm	0.6 cm	1.2 cm	1.8 cm	2.4 cm	3.0 cm	3.6 cm	4.2 cm	4.8 cm
3 cm	0.9 cm	1.8 cm	2.7 cm	3.6 cm	4.5 cm	5.4 cm	6.4 cm	7.3 cm
4 cm	1.2 cm	2.4 cm	3.6 cm	4.8 cm	6.1 cm	7.3 cm	8.5 cm	9.7 cm
5 cm	1.5 cm	3.0 cm	4.5 cm	6.1 cm	7.6 cm	9.1 cm	10.6 cm	12.1 cm
6 cm	1.8 cm	3.6 cm	5.4 cm	7.3 cm	9.1 cm	10.9 cm	12.7 cm	14.5 cm
7 cm	2.1 cm	4.2 cm	6.4 cm	8.5 cm	10.6 cm	12.7 cm	14.8 cm	16.9 cm
8 cm	2.4 cm	4.8 cm	7.3 cm	9.7 cm	12.1 cm	14.5 cm	16.9 cm	19.4 cm

90-g tube:

1.78 cm (0.70 in) = approximately 1 g



Formula: Estimated length of SANTYL® Ointment ("SO") needed from 90-g tube
= Wound area x nickel depth x SO density x approx. length of 1 g of SO
= (X cm^2) x (0.2 cm) x (0.85 g/cm^3) x (1.78 cm/g)

Not intended to supersede independent clinical judgment or institutional/agency protocol.

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.

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Standard Practice Application* for Topical Medications: Collagenase SANTYL® Ointment

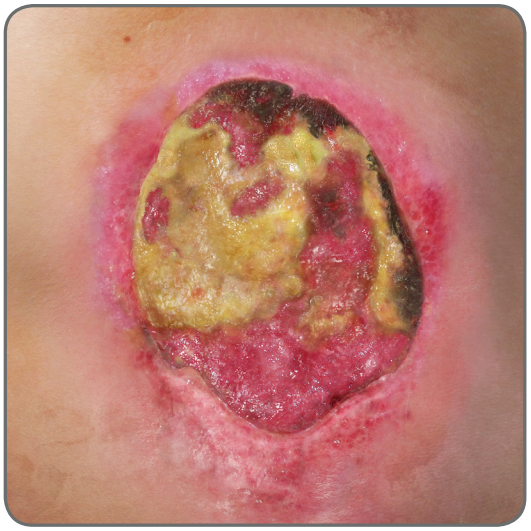
1. Verify and confirm patient has received prescription in accordance with physician order
2. Identify patient per agency policy
3. Knock on patient's door for permission to enter
4. Provide privacy for patient
5. Ask patient if they are experiencing any pain, and report per agency policy
6. Explain application to the patient
7. Clean hands per agency policy
8. Set up a clean field near patient
9. Assemble supplies on a clean field per agency policy
10. Don/apply gloves
11. Remove soiled dressing. Dispose of in appropriate container per agency policy
12. Remove gloves
13. Clean hands
14. Remove as much loose debris from the wound as possible
15. 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
16. If necessary, have a ***properly licensed clinician*** crosshatch thick eschar with a #10 blade to ensure optimal surface contact
17. Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured
18. Apply SANTYL® Ointment at 2 mm thickness (approximately nickel thickness)
19. Apply SANTYL® Ointment within the area of the wound
20. Apply once daily (or more frequently if the dressing becomes soiled, as from incontinence). Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture
21. Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture
22. Do not use dressings containing silver (Ag) or iodine (I_2) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment
23. Gather dirty supplies and bag. Dispose of soiled bag per agency policy
24. Remove gloves and cleanse hands
25. Assure patient is safe and comfortable
26. Document application per agency policy which may include wound measurements, assessment of the wound, patient tolerance and pain level at the completion of the treatment
27. If necessary, determine there is enough medication for upcoming topical application. If not, contact ordering provider for prescription refill
28. When necessary, provide application guide to patient and/or caregiver
29. Educate on proper storage of prescription per package insert

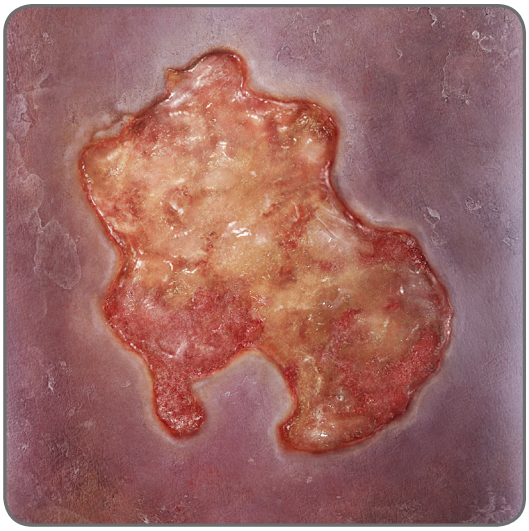
*The above recommendations are based on standards and practices commonly utilized by PDQWC members related to the application of Collagenase SANTYL® Ointment in their respective practices; such recommendations are not intended to supersede independent clinical judgment or agency protocols. Where laws, regulations, or other protocols/guidelines require or suggest an alternative approach to be taken, a clinician should follow such measures.

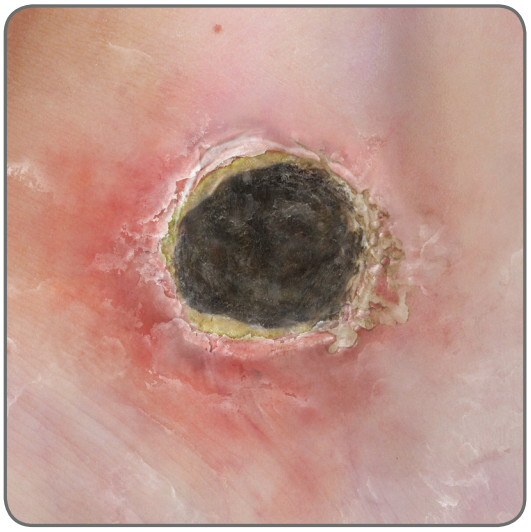
Demonstration of Collagenase SANTYL® Ointment Application

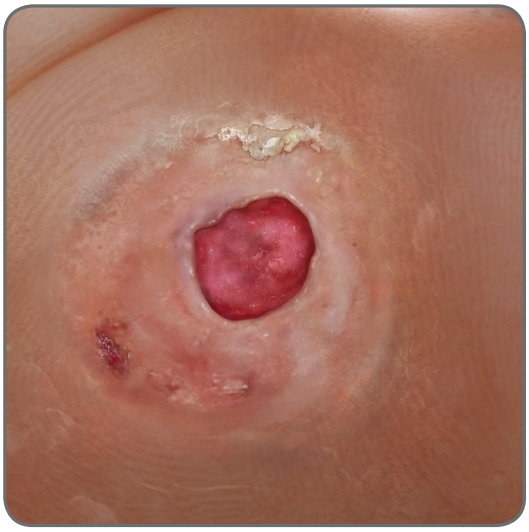
Applying Collagenase SANTYL® Ointment to a Wound

Directions: Select a wound, gather supplies and apply demonstration ointment to learn how to apply Collagenase SANTYL® Ointment per package insert.









This is for demonstration purposes only.
Not intended to supersede independent clinical judgment or institutional/agency protocol.

Collagenase Santyl®
Ointment 250 units/g

Rx only

DESCRIPTION: Collagenase SANTYL® 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.[1] Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelization of dermal ulcers and severely burned areas. [2, 3, 4, 5, 6] Collagen in healthy tissue or in newly formed granulation tissue is not attacked. [2, 3, 4, 5, 6, 7, 8] 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® Ointment is indicated for debriding chronic dermal ulcers [2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18] and severely burned areas. [3, 4, 5, 7, 16, 19, 20, 21]

CONTRAINDICATIONS: Collagenase SANTYL® 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® 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® Ointment.

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 Collagenase SANTYL® 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® 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® 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® 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® 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® Ointment. Should the infection not respond, therapy with Collagenase SANTYL® Ointment should be discontinued until remission of the infection.
3 – Collagenase SANTYL® 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® Ointment should be terminated when debridement of necrotic tissue is complete and granulation tissue is well established.

HOW SUPPLIED: Collagenase SANTYL® 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® 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.** Zimmermann, WE., 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., Behounkova, 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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Reorder Nos.
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0064-5010-30 (30 g tube)
0064-5010-90 (90 g tube)

140385-0814

Notes

References: 1. Motley TA, Lange DL, Dickerson JE, Slade HB. Clinical outcomes associated with serial sharp debridement of diabetic foot ulcers with and without clostridial collagenase ointment. Wounds. 2014;26:57-64. **2.** Milne CT, Ciccarelli AO, Lassy M. A comparison of collagenase to hydrogel dressings in wound debridement. Wounds. 2010;22:270-274. **3.** Alvarez OM, Fernandez-Obregon A, Rogers RS, Bergamo L, Masso J, Black M. A prospective, randomized comparative study of collagenase and papain-urea for pressure ulcer debridement. Wounds 2002;14:293-301.

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