

Smith+Nephew

Collagenase
SANTYL[◇]

Ointment 250 units/gram

A patient's guide
+ Collagenase
SANTYL[◇] Ointment



What is Collagenase SANTYL[®] Ointment?

SANTYL Ointment is an FDA-approved prescription medicine that removes dead tissue from wounds so they can start to heal.

Healthcare professionals have prescribed SANTYL Ointment for more than 50 years to help clean many types of wounds, including chronic dermal ulcers (such as pressure injuries, diabetic ulcers, and venous ulcers) and severely burned areas.



**+ Out with unhealthy tissue,
in with a healthier wound environment**

SANTYL Ointment helps clean your wound by removing dead tissue, and not harming health tissue. This can allow new, healthy tissue to form.



Frequently asked questions about SANTYL[®] Ointment

What is SANTYL Ointment doing for my wound?

SANTYL Ointment is an enzymatic debrider that actively and selectively removes necrotic/dead tissue from a wound without harming healthy tissue. Removing the barrier of necrotic tissue helps stalled and/or chronic wounds move toward closure.

Are there any precautions when using SANTYL Ointment?

Occasional slight redness has been noted if SANTYL Ointment is placed outside the wound area.

Who should NOT use SANTYL Ointment?

DO NOT use SANTYL Ointment if you have a known allergy or sensitivity to collagenase or any other ingredient in this product. Use this product only if it has been prescribed by your healthcare professional.

The risk information provided herein is not comprehensive. To learn more, talk about SANTYL with your healthcare provider. The FDA-approved product labeling can be found at santyl.com.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Call 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Does SANTYL Ointment harm healthy tissue?

NO. It only selectively removes necrotic tissue.

What should I avoid while using SANTYL Ointment?

Take care not to extend SANTYL Ointment use beyond the wound surface although it does not harm healthy tissue. Make sure to apply the ointment only to the identified wound. Never use SANTYL Ointment in or around your eyes, mouth, or any unprotected orifice.

How should I store SANTYL Ointment?

DO NOT refrigerate SANTYL Ointment or expose it to heat. Store SANTYL Ointment at room temperature (no higher than 25° C or 77° F).



Keep SANTYL Ointment and all medicines out of the reach of children

**+ For the best results,
always use the correct amount of ointment**

Always use SANTYL Ointment as instructed by your healthcare professional and according to the instructions in the product packaging.

Your healthcare professional will show you how much SANTYL Ointment your wound needs. Apply the correct amount as instructed by your healthcare professional, SANTYL Ointment should be applied directly to the wound bed with the thickness of a nickel (approximately 2mm), whenever possible.

Ask your healthcare professional or pharmacist right away if you have any other questions or need additional information about SANTYL Ointment. It is also a good idea to read the product packaging every time you get a refill, to remind you of the right way to use the medicine.



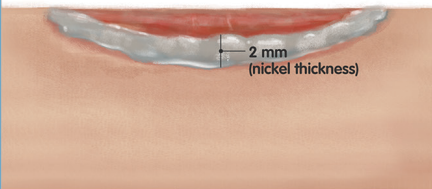
How do I apply SANTYL^o Ointment?

+ 4 simple steps to apply SANTYL Ointment



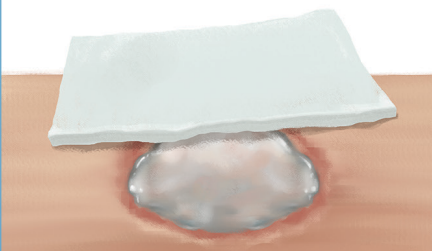
1 Cleanse

Gently cleanse the wound with sterile saline, or as directed by your health care professional.



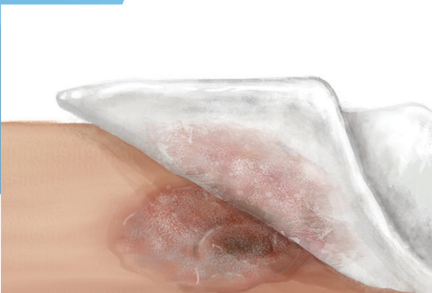
2 Apply

Apply SANTYL Ointment directly to the wound at 2mm thickness. It should be about the **thickness of a nickel** lying flat.



3 Cover

Wounds with sufficient wound fluid will have enough moisture for product to be effective, but a dry wound may require additional moisture. Add moisture, as with a saline moistened gauze, compatible wound gel, and/or appropriate cleansers.



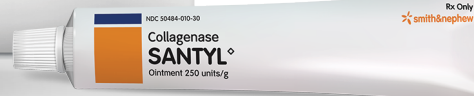
4 Change

Change dressings daily, or as instructed by your healthcare professional, to help remove dead tissue from the wound area to help advance the healing process.



Call your pharmacy to make sure
your prescription is available

SANTYL[®] Ointment is covered by all Medicare Part D plans.
Visit www.santyl.com for more information.



Important Safety Information

SANTYL Ointment is used to remove damaged tissue from chronic skin ulcers and severely burned areas. Do not use if you have shown hypersensitivity to collagenase. Occasional slight redness may occur if SANTYL Ointment is placed outside the wound area. Precautions should be taken to avoid detergents or cleansing solutions that are acidic or basic in nature, as raising or lowering of the Ointment's pH can lower the effectiveness. Caregivers to debilitated patients should closely monitor the application site to ensure that the area is not becoming infected. The risk information provided herein is not comprehensive. To learn more, talk about SANTYL with your health care provider. The FDA-approved product labeling can be found at <https://www.santyl.com/>. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

Advanced Wound Management

Smith & Nephew, Inc.
Fort Worth, TX 76109
USA

www.smith-nephew.com
www.santyl.com

Customer Care Center

T 800 876-1261
F 727 392-6914

[®]Trademark of Smith+Nephew
©2020 Smith+Nephew, Inc.

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 epithelialization 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 the following sizes:
30 g tube NDC 50484-010-30
90 g tube NDC 50484-010-90

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, 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., Behoukova, 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 – Bardfield, 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.

Manufactured by:
Smith & Nephew, Inc.
Fort Worth, Texas 76109
US Gov't License #2004

Marketed by:

 **smith&nephew**

1-800-441-8227
Smith & Nephew, Inc.
Fort Worth, Texas 76109

© 2016 Smith & Nephew, Inc.
SANTYL is a registered trademark of Smith & Nephew, Inc.
140749-0316