

COLLAGENASE SANTYL- collagenase santyl ointment
SMITH & NEPHEW, INC

COLLAGENASE SANTYL[◇] ointment
250 units/g
[SMITH & NEPHEW, INC]

R_x 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 the following sizes:

30 g tube NDC 50484-010-30

90 g tube NDC 50484-010-90

REFERENCES

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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

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140749-0316

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

| | | | | | |
|--|---|--|----------------|--|--|
| <p>30 g</p> | <p>NDC 50484-010-30</p> <p>Collagenase SANTYL[◊] Ointment 250 units/g</p> | | <p>Rx Only</p> | <p>3 50484 01030 0</p> | |
| <p>(Derived from <i>Clostridium histolyticum</i>) For enzymatic debridement. 250 units per gram. No U.S. standard of potency. Contains no preservative. For external use only. See enclosed prescribing information. Do not store above 25°C (77°F). Sterility guaranteed until tube is opened. Invert cap to puncture tube.</p> | | | | <p>106641-0316</p> | |
| <p>30 g</p> | <p>NDC 50484-010-30</p> <p>Collagenase SANTYL[◊] Ointment 250 units/g</p> | | <p>Rx Only</p> | <p>Manufactured by Smith & Nephew, Inc. Fort Worth, TX 76109 U.S. Gov't License #2004 Marketed by Smith & Nephew, Inc. Fort Worth, TX 76109 *SANTYL is a registered trademark of Smith & Nephew, Inc. 1-800-441-8227</p> | |

TUBE LABEL.PRINCIPAL DISPLAY PANEL

The flat layout consists of three main panels and a side panel. Each panel contains the following information:

- Top Panel:**
 - NDC 50484-010-30
 - 30 g**
 - Collagenase SANTYL[◊]**
 - Ointment 250 units/g
 - smith&nephew logo
 - Rx Only
- Middle Panel:**
 - (Derived from *Clostridium histolyticum*) For enzymatic debridement. 250 units per gram. No U.S. standard of potency. Contains no preservative. Invert cap to puncture tube.
 - For external use only. See attached prescribing information. Do not store above 25°C (77°F). Sterility guaranteed until tube is opened.
 - Manufactured by Smith & Nephew, Inc., Fort Worth, TX 76109. U.S. Gov't License #2004. Marketed by Smith & Nephew, Inc., Fort Worth, TX 76109. *SANTYL is a registered trademark of Smith & Nephew, Inc.
 - 117313-0316
 - Barcode: 3 50484 01030 0
- Bottom Panel:**
 - NDC 50484-010-30
 - 30 g**
 - Collagenase SANTYL[◊]**
 - Ointment 250 units/g
 - smith&nephew logo
 - Rx Only
 - 1-800-441-8227
- Side Panel:**
 - Barcode: 3 50484 01030 0

COLLAGENASE SANTYL

collagenase santyl ointment

Product Information

| | | | | |
|---|---|---|-----------------------------|---------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:50484-010 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| COLLAGENASE CLOSTRIDIUM HISTOLYTICUM (UNII: 9X7O8V25IT) (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM - UNII:9X7O8V25IT) | | COLLAGENASE CLOSTRIDIUM HISTOLYTICUM | 250 [arb'U] in 1 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| Product Characteristics | | | | |
| Color | WHITE (WHITE TO OFF WHITE) | Score | | |
| Shape | | Size | | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:50484-010-30 | 1 in 1 CARTON | 10/18/2006 | |
| 1 | | 30 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:50484-010-90 | 1 in 1 CARTON | 03/10/2014 | |
| 2 | | 90 g in 1 TUBE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA101995 | 10/18/2006 | | |

Labeler - SMITH & NEPHEW, INC (827731451)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Renaissance Lakewood LLC | | 077744035 | MANUFACTURE(50484-010) , pack(50484-010) , analysis(50484-010) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|--|
| HALO PHARMACEUTICALS, INC. | | 829609168 | MANUFACTURE(50484-010) , pack(50484-010) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Smith & Nephew, Inc. | | 125458849 | analysis(50484-010) |

Revised: 5/2019

SMITH & NEPHEW, INC