Enzymatic Debridement With Collagenase SANTYL® Ointment

Pressure Ulcer Stage 4—Knee

Pressure Ulcer Unstageable—Hip

Diabetic Foot Ulcer

Burn

Non-progressing Venous Leg Ulcer

Description


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 burn without necrotic tissue

Progression

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 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.

Photographs used with permission by: NPUAP.org Copyright ©2011 Gordian Medical, Inc. dba American Medical Technologies; Mobile Wound Solutions, 2012; Paul Glat, MD, 2013.

Measurement and Application Protocol for Collagenase SANTYL® Ointment

1 CLEANSE

2 APPLY

3 COVER

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

» 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

» 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)

» Do not use dressings containing silver (Ag) or iodine (I₂) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment

» Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture

» 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

90-g tube: 1.78 cm (0.70 in) = approximately 1 g
### 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.

<table>
<thead>
<tr>
<th>20-g tube: 3.04 cm (1.20 in) = approximately 1 g</th>
<th>90-g tube: 1.78 cm (0.70 in) = approximately 1 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CLEANSE</td>
<td></td>
</tr>
<tr>
<td>- Remove as much loose debris from the wound as possible</td>
<td></td>
</tr>
<tr>
<td>- 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</td>
<td></td>
</tr>
<tr>
<td>- When necessary, crosshatch thick eschar with a #10 blade to ensure optimal surface contact</td>
<td></td>
</tr>
<tr>
<td>2 APPLY</td>
<td></td>
</tr>
<tr>
<td>- Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured</td>
<td></td>
</tr>
<tr>
<td>3 COVER</td>
<td></td>
</tr>
<tr>
<td>- Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture</td>
<td></td>
</tr>
<tr>
<td>- Do not use dressings containing silver (Ag) or iodine (I2) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment</td>
<td></td>
</tr>
</tbody>
</table>

**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

### Enzymatic Debridement With Collagenase SANTYL® Ointment

**Measurement and Application Protocol**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CLEANSE</td>
<td>Remove as much loose debris from the wound as possible</td>
</tr>
<tr>
<td>2 APPLY</td>
<td>Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured</td>
</tr>
<tr>
<td>3 COVER</td>
<td>Wounds with sufficient exudate will naturally activate the collagenase enzyme, but a dry wound bed may require additional moisture</td>
</tr>
</tbody>
</table>

**Principal Indications**
- Active, selective debridement
- Wounds with sufficient exudate
- Non-progressing wounds
- Severe burns

**Warning**
- Do not use dressings containing silver (Ag) or iodine (I2) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment

**Administration**
- Apply SANTYL® Ointment within the area of the wound
- Apply once daily (or more frequently if the dressing becomes soiled, as from incontinence)
- 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
- Crosshatch thick eschar with a #10 blade to ensure optimal surface contact

**Contraindications**
- Do not use SANTYL® Ointment on non-healing ulcers
- Do not use on skinfold areas
- Do not use SANTYL® Ointment in areas that are thrombosed or ischemic

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

**Photographs used with permission by:**
- NPUAP.org Copyright ©2011 Gordian Medical, Inc.
- Mobile Wound Solutions, 2012
- Paul Glat, MD, 2013

---

**Herbal Extract**

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collagenase</td>
<td>Enzyme that degrades extracellular matrix proteins</td>
</tr>
</tbody>
</table>

**Full Directions for Use**

- Apply directly to the wound or to a sterile gauze pad, which is then applied to the wound and properly secured
- Apply once daily (or more frequently if the dressing becomes soiled, as from incontinence)
- 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
- Crosshatch thick eschar with a #10 blade to ensure optimal surface contact

**References**

- Reference: Smith & Nephew, Inc., 2014
- ©2014 Smith & Nephew, Inc. SANTYL is a registered trademark of Smith & Nephew, Inc.
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. Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelization of dermal ulcers and severely burned areas. 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 and severely burned areas. It possesses the unique ability to digest collagen in necrotic tissue. It is also desirable to remove, with forceps and scissors, as much loosened 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. 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.

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. Delayed 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.

DOSE 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 No. 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. It is available in 15 gram, 30 gram, and 90 gram tubes. Do not store above 25°C (77°F). Sterility guaranteed until tube is opened.