

LIDOTREX- dressing, wound and burn, hydrogel w/drug and/or biologic
Sterling-Knight Pharmaceuticals, LLC

Lidotrex Gel
Prescription Only | Rx Only

Lidotrex is a soothing wound gel that promotes a moist wound environment that is ideal for the healing process.

Directions:

Cleanse wound then apply Lidotrex to the wound and skin surrounding the wound 3 - 4 times daily.

Indications:

For the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Warnings:

External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

Caution:

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Storage:

Store at 25°C (77°F): excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

Ingredients:

Water, Lidocaine HCl, Collagen, Aloe Vera gel, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.

CALL YOUR DOCTOR ABOUT SIDE EFFECTS:

Call your doctor about side effects. You may report side effects to Sterling Knight Pharmaceuticals, LLC at 1-888-460-1531 or the FDA at 1-800-FDA-1088.

How Supplied:

Lidotrex wound gel is supplied as a gel in:
1 oz. (28.33g) tube, NDC 69336-835-30

Distributed By:

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Rev 012518-1

Principal Display Panel

The Principal Display Panel (PDP) for Lidotrex is a rectangular label with a purple and blue geometric design on the left side. It contains the following information:

- Sterling | Knight PHARMACEUTICALS** logo in the top left.
- Rx Only** in the top right.
- NDC 69336-835-30** in the center.
- Lidotrex** in large blue font in the center.
- (Lidocaine 2% and Collagen 1.2% and Aloe Vera 1%)** in smaller blue font below the product name.
- NET WT. 1 oz. (28.33 g)** in the bottom right.
- Directions:** Cleanse wound then apply Lidotrex to the wound and skin surrounding the wound 3 - 4 times daily.
- Indications:** For the local management of painful skin wounds, including:
 - Pressure ulcers
 - Venus stasis ulcers
 - Superficial wounds and scrapes
 - 1st and 2nd degree burns
- Warnings:** External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.
- Caution:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Storage:** Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].
- Ingredients:** Water, Lidocaine HCl, Collagen, Aloe Vera gel, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.
- Manufactured for:** Sterling-Knight Pharmaceuticals, LLC | Ripley, MS 38663
- Dispense in Original Container**
- Item 930** and **Rev 032017-1** in the bottom right.
- A **barcode** with the numbers **69336 83530 0** below it.

LIDOTREX

dressing, wound and burn, hydrogel w/drug and/or biologic

Product Information

Product Type	PREScription MEDICAL DEVICE	Item Code (Source)	NHRIC:69336-835
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A)	
BOVINE TYPE I COLLAGEN (UNII: FHJ3ATL51C)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	

Product Characteristics

(SPLSTERILEUSE)	false
(SPLMRISAFE)	true

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-835-30	28.33 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
premarket notification	K020540	01/01/2017	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Revised: 3/2018

Sterling-Knight Pharmaceuticals, LLC