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
• 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.

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:

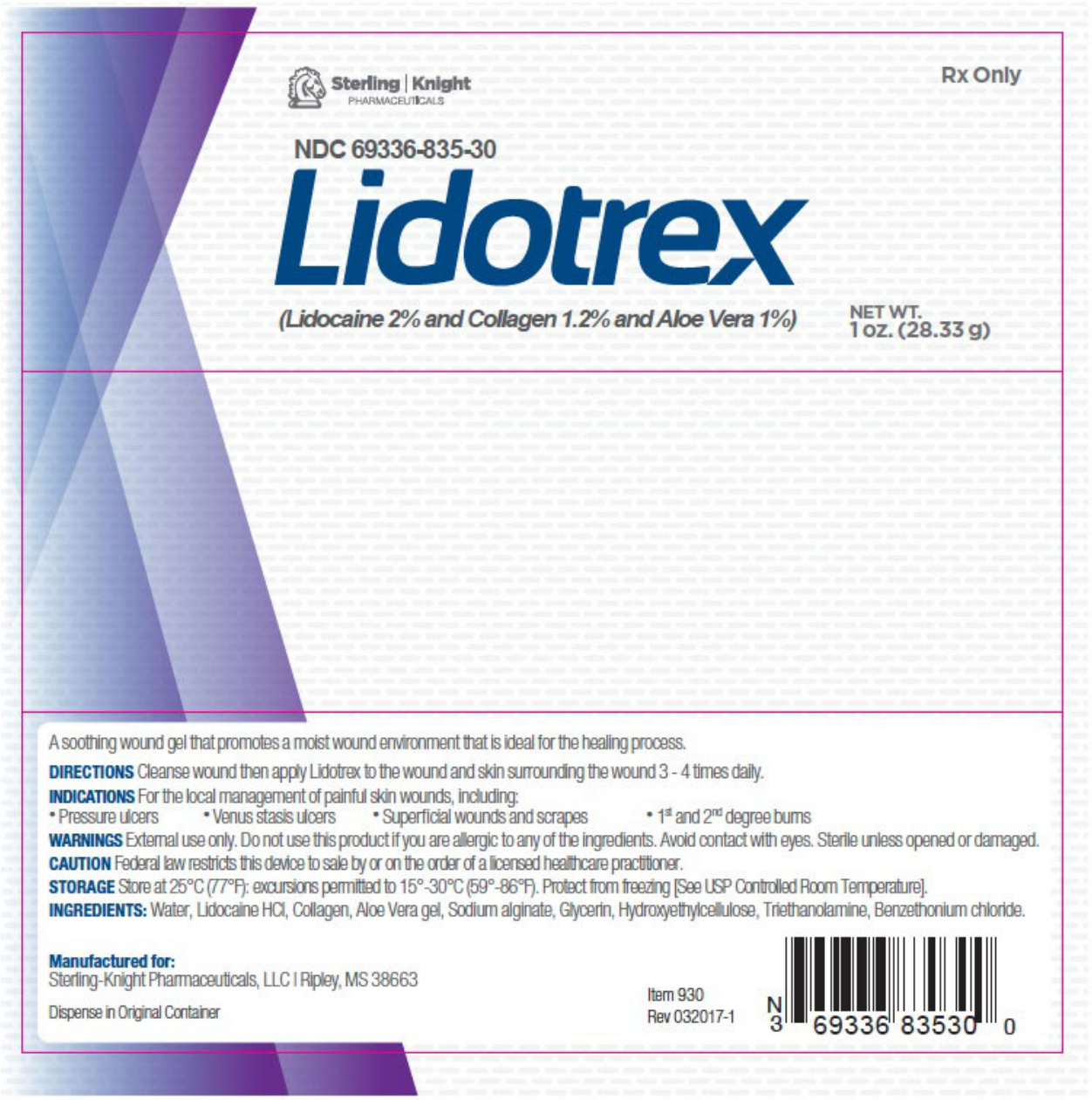
Lidotrex wound gel is supplied as a gel in:
1 oz. (28.33g) tube, NDC 69336-835-30

Distributed By:

Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

Rev 012518-1

Principal Display Panel



LIDOTREX

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

Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:69336-835

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 MPA.S 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