

## **7T LIDO- dressing, wound and burn, hydrogel w/drug and/or biologic gel**

**7T Pharma LLC**

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### **7T LIDO GEL**

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### **7T LIDO GEL**

**Rx Only**

**For external use only**

**Not for ophthalmic use**

### **7T LIDO GEL Description**

**7T LIDO GEL** is a soothing viscous hydrogel wound dressing containing lidocaine 2% as a topical anesthetic intended for use in the local management of painful skin wounds. **7T LIDO GEL** also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

**7T LIDO GEL** contains: Lidocaine HCl, Benzethonium Chloride, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Glycerin, Hydrolyzed Collagen, Hydroxyethylcellulose, Sodium Alginate, Tocopheryl Acetate (Vitamin E), Triethanolamine.

### **INDICATIONS AND USES**

**7T LIDO GEL** is intended to be used under the supervision of a healthcare professional to be used as local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

### **WARNINGS**

For external use only. Do not use this product if you are allergic to any of the ingredients listed. Avoid contact with eyes. Sterile unless opened or damaged. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician. If ingested, get medical help or contact Poison Control Center right away.

**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

This medication should be used as directed by your physician during pregnancy or while breastfeeding. Consult your doctor about the risks and benefits.

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician

### **ADVERSE REACTIONS**

On rare occasions, the gel may cause temporary redness, stinging, burning or irritation and normally disappear when the medication is discontinued.

### **How is 7T LIDO GEL Supplied**

**7T LIDO GEL** is supplied as a gel in:

3 oz. (85g) tube

NDC: 70645-804-26

**Store at 20°-25°C (68° to 77°F); Keep away from heat and protect from freezing. [See USP Controlled Room Temperature.]**

**Manufactured for:**

7T Pharma, LLC  
Los Angeles, CA 90064

**PRINCIPAL DISPLAY PANEL**

**7T Lido Gel**

Rx ONLY

NDC 70645-804-26

3oz (85g)

*A wound gel that soothes and promotes a moist wound environment that is ideal for the healing process.*

**Directions:** Apply 7T Lido Gel to the cleansed wound and skin surrounding the wound 3-4 times daily.

Contains Lidocaine HCl 2% with Aloe Vera and Collagen

# 7T Lido Gel

*7T Lido Gel is intended for the local management of painful skin wounds, including pressure ulcers, venous stasis ulcers, superficial wounds and scrapes, and first and second 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 physician.

**Storage:** Store at 20° - 25° C (68° to 77° F); excursions permitted to 15° - 30° C (59° - 86° F). Keep away from heat and protect from freezing [See USP Controlled Room Temperature].

**Ingredients:** Lidocaine HCl, Benzethonium Chloride, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Glycerin, Hydrolyzed Collagen, Hydroxyethylcellulose, Sodium Alginate, Tocopheryl Acetate (Vitamin E), Triethanolamine.

**Manufactured for:**

7T Pharma, LLC  
Los Angeles, CA 90064

Rx ONLY

NDC: 70645-804-26

3oz (85g)

Made in USA



## 7T LIDO

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

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:70645-804	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 mg in 100 mg	
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)		BENZETHONIUM CHLORIDE	0.5 mg in 100 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)				
HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%) (UNII: L605B5892V)				
SODIUM ALGINATE (UNII: C269C4G2ZQ)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
TROLAMINE (UNII: 9O3K93S3TK)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:70645-804-26	85000 mg in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
PREMARKET NOTIFICATION	K020540	08/01/2018		

**Labeler** - 7T Pharma LLC (080220022)

Revised: 10/2018

7T Pharma LLC