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

7T LIDO GEL 7T Pharma, LLC

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:

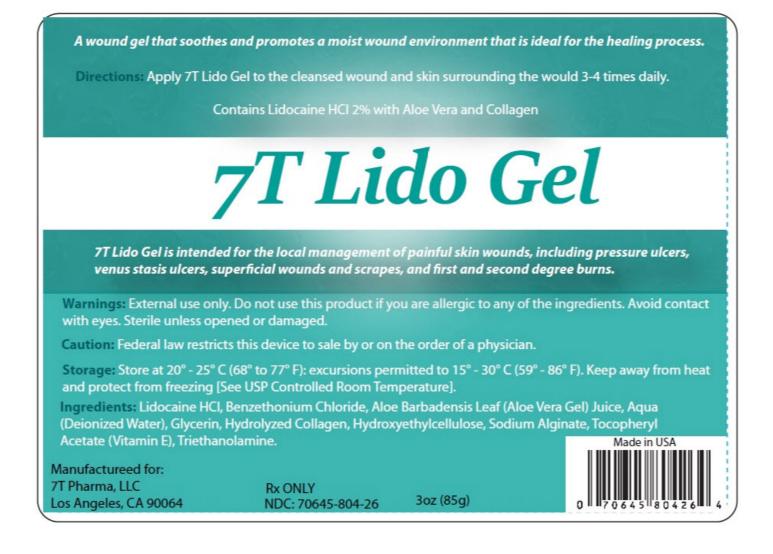
7T Pharma, LLC Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

7T Lido Gel

Rx ONLY NDC 70645-804-26

3oz (85g)



7T LIDO

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

Product Information

Product T ype			MEDICAL DEVICE Item Code		ode (Source)	NHR	IRIC:70645-804	
Route of A	dministrati	ion	TOPICAL					
Active Ing	gredient/	Active Moi	ety					
Ingredient Name					Basis of Strength		Strei	ıgth
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)					IDOCAINE HYDROCHLORIDE ANHYDROUS		2 mg in 100 r	ng
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM - UNII:1VU15B70BP)					BENZETHONIUM CHL	ENZETHONIUM CHLORIDE		mg
• -								
Inactive I	ngredien	Its	T . 11 . T				<u>.</u>	
Ingredient Name ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)							Stren	gth
ALUE VERA WATER (UN			X)					
GLYCERIN	•	,						
	,		II: 8JC99XGU4W)					
			0 MPA.S AT 1%) (UNII: L	605B5892V)				
		JNII: C269C4G2						
			UNII: 9E8X80D2L0)					
TROLAMIN			,					
		,						
Packagin	g							
# Item	Code		Package Description	ı	Marketing Star	t Date I	Marketing End	d Da
1 NHRIC:70	645-804-	85000 mg in 1	TUBE; Type 0: Not a Con	nbination Pro	duct			
	ing Info	rmation						
Marketi	U U		Application Number or Monograph Citat			n Marketing Start Date Mark		
	ng Catego	ry Applic	ation Number or Mono	graph Citat	ion Marketing Star	t Date	Marketing End	1 Dat

Labeler - 7T Pharma LLC (080220022)

Revised: 10/2018

7T Pharma LLC