LEVIGOLT- lidocaine/menthol cream cream
Topicare Management, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Description

LevigoLT is a Lidocaine HCI 4% and Menthol 1% topical anesthetic and analgesic cream indicated to temporarily relieve minor pain.

Active Ingredients

Each gram of LevigoLT contains:

Lidocaine HCI 4% (40mg) Topical Anesthetic

Menthol 1% (10mg) Topical Analgesic

Purpose

Temporarily relieves minor pain associated with: arthritis, simple backache, sprains, bruises, muscles soreness, cramps

Warnings

For external use only. Do not use on large areas of the body or on cut, irritated or swollen skin, puncture wounds, or for more than one week without consulting a doctor.

When Using This Product

When using this product use only as directed. Read and follow all directions and warnings on this carton. *was hands with soap and water after applying *rare cases of serious burns have been reported with product of this type *do not bandage or apply local heat (such as heating pads) to the area of use or use with a medicated patch *avoid contact with eyes and mucous membranes *atransient burning sensation may occur upon application but generally disappears in several days

Ask Doctor

Stop use and ask a doctor if *condition worsens *redness is present * irritation develops *symptoms persist more than 7 days or clear up and occur again within a few days *you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

Pregnancy or Breast Feeding

If pregnant or breast feeding, ask a health professional before use.

Keep Out of Reach of Children

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poinson Control Center right away.

Indications & Usage

Directions: Adults and children over 12 year: *apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24-hour period *after applying, wash hands with soap and water *children 12 years or younger: ask a doctor.

Questions or Comments

For questions or comments, call 1-800-635-3696.

Dosage and Administration

Distributed by: Topicare Therapeutics, LLC. 1925 Longmire Rd. Building 2, Conroe, TX 77304

Made in U.S.A. of U.S. and imported materials

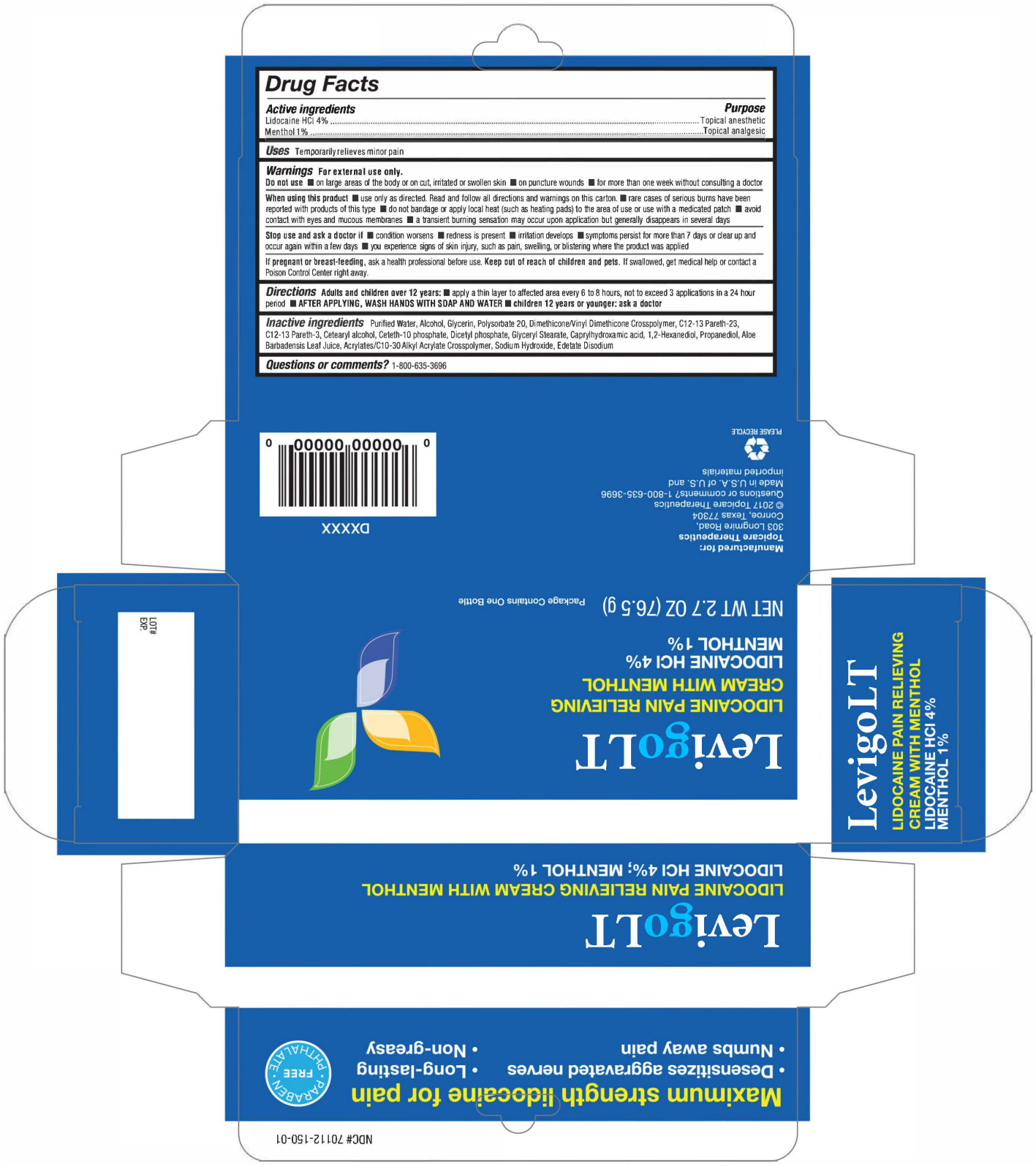
Inactive Ingredients

Purified Water, Alcohol, Glycerin, Polysorbate 20, Dimethicone/Vinyl Dimethicone Crosspolymer, C12-13 Pareth-23, C12-13 Pareth-3, Cetearyl alcohol, Ceteth-10 phosphate, Dicetyl phosphate, Glyceryl Stearate, Caprylhydroxamic acid, 1,2-Hexanediol, Propanediol, Aloe Barbadensis Leaf Juice, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Hydroxide, Edetate Disodium

Storage and Handling

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing.

Package Label. Principal Display Panel



LEVIGOLT

lidocaine/menthol cream cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70112-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-13 PARETH-23 (UNII: J1WW1510L4)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
C12-13 PARETH-3 (UNII: DMC6N3419L)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70112-150-01	1 in 1 CARTON	05/09/2017	
1		76.5 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
OTC monograph not final	part348	05/09/2017	

Labeler - Topicare Management, LLC (079902303)

Establishment

Name	Address	ID/FEI	Business Operations
Topicare Management, LLC		079902303	manufacture(70112-150)

Revised: 5/2017 Topicare Management, LLC