LIDOCREAM 4- lidocaine cream
Golden Touch 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.

LidoCream 4

Active ingredient

Lidocaine 4% W/W

Purpose

Topical Anesthetic

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

Uses

For the temporary relief of pain and itching due to

- minor burns
- minor skin irritations
- minor cuts
- scrapes
- sunburn
- insect bites

Warnings

For external use only

When using this product

- Avoid contact with the eyes
- Do not use in large quantities particularly over raw surfaces or blistered areas.
- Do not exceed recommended dosage unless directed by a doctor

Stop use and ask a doctor if

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- Symptoms clear up and return within a few days
- notice any unusual effects such as blurred vision, dizziness or drowsiness, difficulty in breathing, trembling, chest pain or irregular heart beat

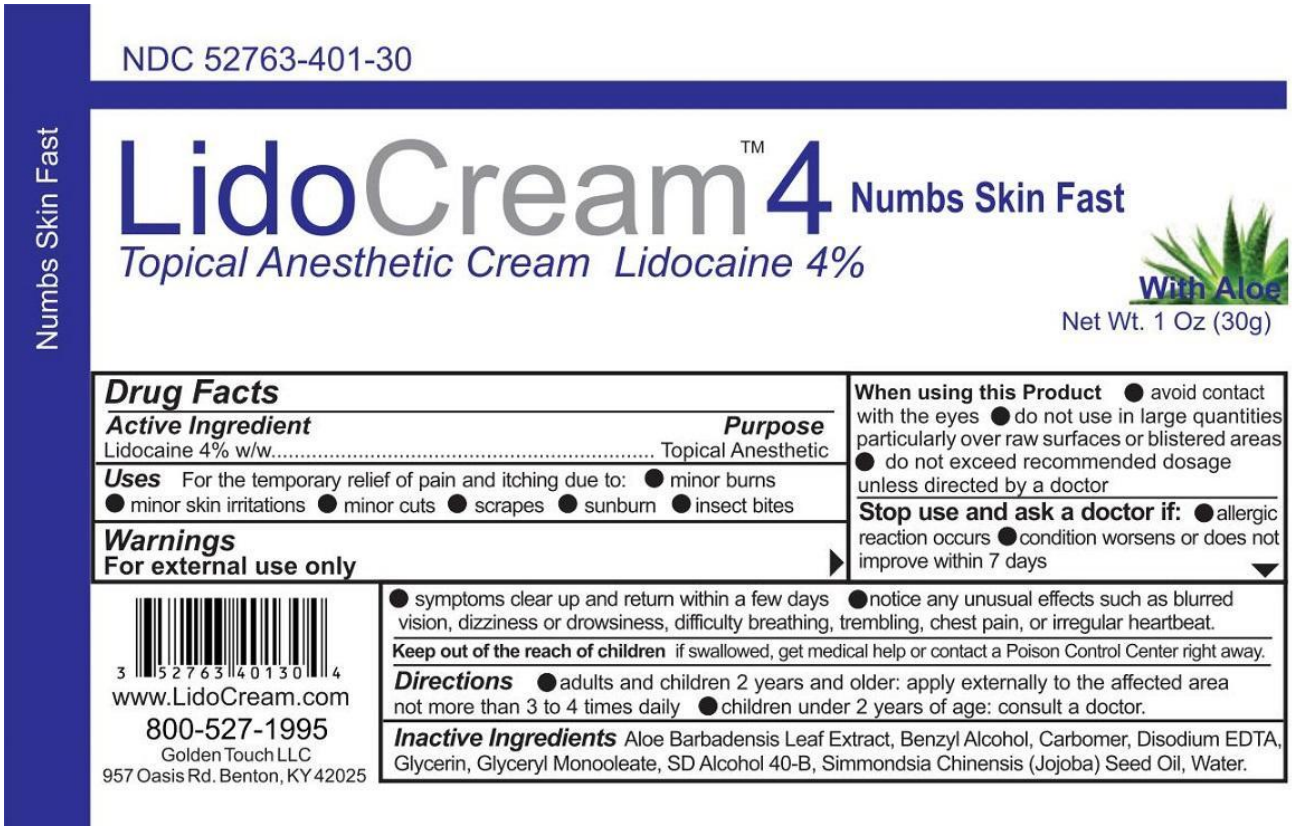
Directions

- Adults and children 2 years and older: apply externally to the affected area not more than 3 to 4 times daily
- Children under 2 years of age: consult a doctor

Inactive ingredients

Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Monooleate, SD Alcohol 40-B, Simmondsia Chinensis (Jojoba) Seed Oil, Water

Packaging



LIDOCREAM 4

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52763-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
ALCOHOL (UNII: 3K9958V90M)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52763-401-30	1 in 1 CARTON		
1		30 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 final	part346	12/01/2010	

Labeler - Golden Touch LLC (194284147)

Establishment

Name	Address	ID/FEI	Business Operations
Golden Touch LLC		194284147	manufacture(52763-401)

Revised: 11/2015 Golden Touch LLC