#### 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.

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#### 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

#### 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 Numbs Skin Fast



Net Wt. 2 Oz (60g)

Drug Facts	Drug Facts (continued)	
Active Ingredient Purpose	Surfaces or plistered areas and do no	
Lidocaine 4% w/wTopical Anesthetic Uses For the temporary relief of pain and itching due to ● minor burns ● minor skin irritations	Stop use and ask a doctor in within 7 days  symptoms clear up blurred vision, dizziness or drowsin	
Warnings	Keep out of the reach of children	
For external use only	<b>Directions</b> • adults and children than 3 to 4 times daily • children	
	Inactive Ingredients Aloe Bar Glycerin, Glyceryl Monooleate, SD	
3 5 2 7 6 3 4 0 1 6 0 1	www.LidoCream.com	

NDC 52763-401-60

	Drug ruois (contantaca)				
Purpose al Anesthetic	When using this Product surfaces or blistered areas do not		ot use in large quantities particularly over raw directed by a doctor		
ain and itching skin irritations	within 7 days 🔵 symptoms clear up	and return within a few days	condition worsens or does not improve notice any unusual effects such as ng, chest pain, or irregular heartbeat.		
	Keep out of the reach of children right away	n if swallowed, get medical help	o or contact a Poison Control Center		
	<b>Directions</b> • 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.				
1	www.LidoCream.com	800-527-1995	Golden Touch LLC 957 Oasis Rd. Benton, KY 42025		

#### **LIDOCREAM 4**

lidocaine cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:5276	53-401
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingre	edient Name		Basis of Stre	ngth	Strength
LIDO CAINE (UNII: 98PI200987) (LIDO	CAINE - UNII:98PI200987)		LIDOCAINE	4	4 g in 100 g
Inactive Ingredients					
	Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0)	X)				
BENZYL ALCOHOL (UNII: LKG8494V	VBH)				
CARBOMER HOMOPOLYMER TYPE	C (ALLYL PENTAERYTHRIT	OL CROSSLIN	<b>KED)</b> (UNII: 4Q93RC	CW27E)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8	36K)				
GLYCERIN (UNII: PDC6A3C0OX)					
GLYCERYL OLEATE (UNII: 4PC054V7	79 P)				
ALCOHOL (UNII: 3K9958V90M)					
SIMMONDSIA CHINENSIS SEED (UNI	l: D24K2Q1F6H)				
WATER (UNII: 059QF0KO0R)					

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:52763-401-60	1 in 1 CARTON				
1	60 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	12/0 1/20 10			

## Labeler - Golden Touch LLC (194284147)

### Establishment

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

Revised: 11/2015

Golden Touch LLC