SIMPLY NUMB ENDURE- 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.

Simply Numb Endure

Active ingredient

Lidocaine 5% 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

Warnings

For external use only

When using this product

- Avoid contact with the eyes
- Do not put in rectum
- 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
- rectal bleading occurs
- redness irritation swelling pain or other symptoms develop or increase

Directions

- Adults when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- Apply externally to the affected area up to 6 times daily.
- Children under 12 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







Net Wt. 8 Oz (240g)

Drug Facts (continued)
When using this Product ● avoid contact with the eyes ● do not put in rectum ● 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 ● rectal bleeding occurs ● redness, irritation, swelling, pain or other symptoms develop or increase
Keep out of the reach of children if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts (continued)

Directions Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly

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www.SimplyNumb.com 800-527-1995 Golden Touch LLC 957 Oasis Rd. Benton, KY 42025

NDC 52763-602-40

SIMPLY NUMB ENDURE

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52763-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE	5 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 DISO DIUM (UNII: 7FLD9 1C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL OLEATE (UNII: 4PC054V79P)			

ALCOHOL (UNII: 3K9958V90M)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
WATER (UNII: 059QF0KO0R)	

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:52763-602-	240 g in 1 BOTTLE, PUMP; 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	07/08/2014	

Labeler - Golden Touch LLC (194284147)

Establishment				
Name	Address	ID/FEI	Business Operations	
Golden Touch LLC		19 42 8 4 1 4 7	manufacture(52763-602)	

Revised: 11/2015 Golden Touch LLC