LIDOCREAM 10- 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 10

Drug Facts

Active Ingredient

Lidocaine 10% 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 anorectal disorders

Warnings

For external use only

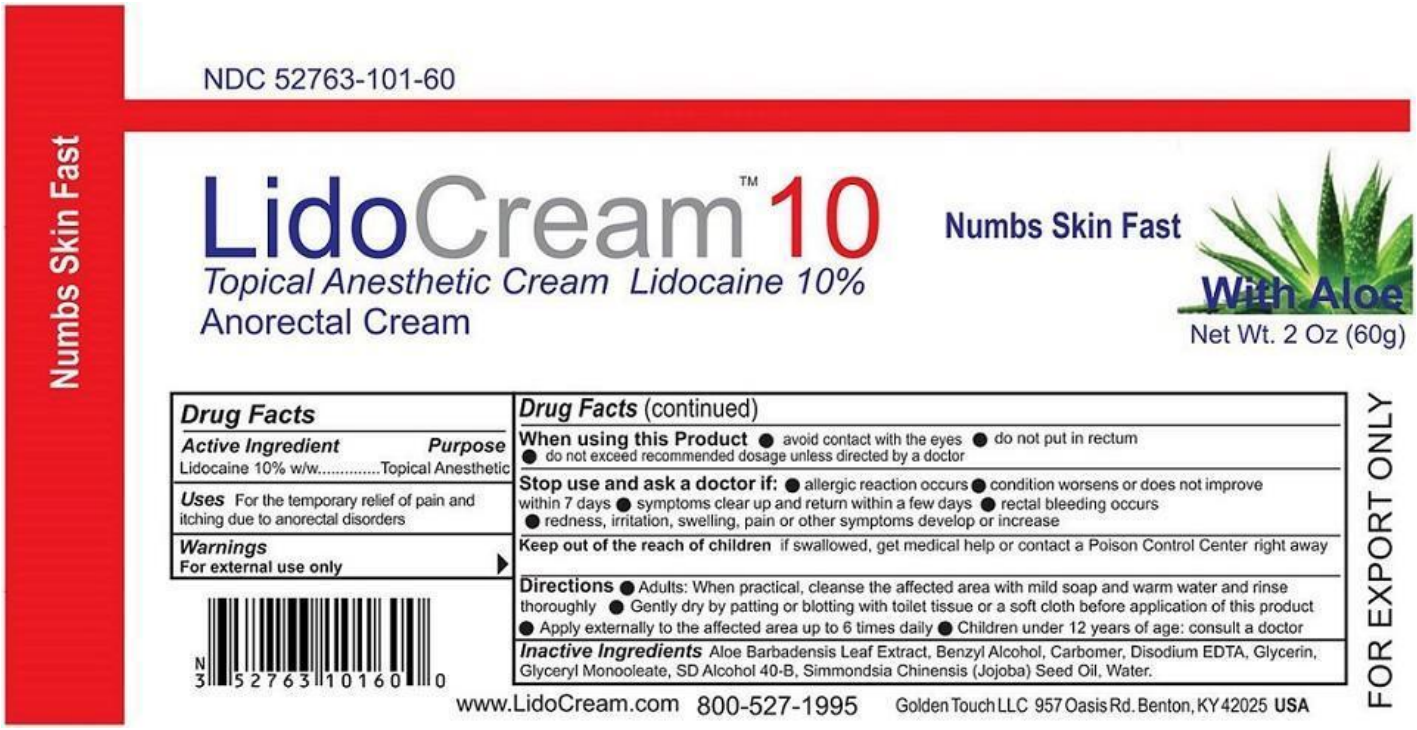
When using this product • avoid contact with eyes • do not put in rectum • do not exceed recommended dosage unless directed by a doctor

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

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 upto 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.

Packaging



LIDOCREAM 10

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52763-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	10 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:52763-101-60	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	05/05/2015	

Labeler - Golden Touch LLC (194284147)

Establishment

Name	Address	ID/FEI	Business Operations
Golden Touch LLC		194284147	manufacture(52763-101)

Revised: 11/2015 Golden Touch LLC