

LIDOCAINE- lidocaine cream
CHENGDU DISCOUNT TRADING CO.LTD

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.

001

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Uses

for temporary relief of local and anorectal discomfort associated with anorectal disorder or inflammation

Warnings

Warnings (For external use only)

Do not use

Do not use this product if

pregnant or breastfeeding , ask a health professional before use.

in case of accidental overdose , get medical help or contact the Poison Control Center immediately.

tamper evident " Do not use this product " if seal is broken or missing.

When using this product

do not exceed the recommended daily dosage unless directed by a doctor.

certain persons can develop allergic reactions to ingredients in this product.

do not put this product into the rectum by using finger or any medical device or applicator.

Stop use

n/a

Keep out of reach of children

Inc case of accidental ingestion , seek medical attention immediately

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 up to 6 times a day,

Children up under 12 years of age: consult a doctor.

Other Information

keep away from direct sunlight or heat.

store in room temperature (59-86 F/15-30 C)

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Iso sorbide, Disodium EDTA , Hydrogenated Polydece, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Acetate, Trideceth-6, Triethanolamine

Package Label - Principal Display Panel

JJ CARE

5% LIDOCAINE

LIDOCAINE CREAM

TOPICAL ANESTHETIC CREAM

CHILD-PROOF PACKAGING

NET WT.: 2 OZ / 56 G

Drug Facts

Active Ingredient

Purpose

Uses:

Warnings

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When using this product

Keep out of reach of children

Lidocaine, 5%

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Drug Facts (Continued)

Directions

Other information

Inactive Ingredients

Questions or comments?

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1-800-420-1183

LIDOCAINE			
lidocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82927-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82927-001-01	56 g in 1 BOX; Type 0: Not a Combination Product	08/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	08/08/2022	

Labeler - CHENGDU DISCOUNT TRADING CO.LTD (705325854)

Establishment

Name	Address	ID/FEI	Business Operations
CHENGDU DISCOUNT TRADING CO.LTD		705325854	manufacture(82927-001)

Revised: 7/2022

CHENGDU DISCOUNT TRADING CO.LTD