

**LIDOCAINE- lidocaine cream**  
**Sichuan Gumo Brand Management 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.*

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**83365-003**

**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 extemal use only )

**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

Incase 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 blottingwith 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 Barbadosis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA , Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Acetate, Trideceth-6, Triethanolamine

## Package Label - Principal Display Panel

	<b>Drug Facts</b> <b>Active Ingredient</b> Lidocaine 5% <b>Purpose</b> Local Anesthetic <b>Uses:</b> for temporary relief of local and anorectal discomfort associated with anorectal disorder or inflammation.	<b>Drug Facts (Continued)</b> <b>Directions</b> • 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 the product. • Apply up to 6 times a day. • Children up under 12 years of age: consult a doctor.
	<b>Warnings</b> (For external use only) <b>Do not use this product if</b> • pregnant or breastfeeding; ask a health professional before use. • in case of accidental overdose, get medical help or contact the Poison Control Center immediately. • further sores: "Do not use this product" if seal is broken or missing. <b>When using this product</b> • 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.	<b>Other Information</b> • keep away from direct sunlight or heat. • store in room temperature (59-86 F/15-30 C).
	<b>Keep out of reach of children</b> In case of accidental ingestion, seek medical attention immediately.	<b>Inactive Ingredients</b> Allantoin, Aloe Barbadosis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA, Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Acetate, Trideceth-6, Triethanolamine.
		<b>Questions or comments?</b> 1-833-420-1183

## LIDOCAINE

lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83365-003
<b>Route of Administration</b>	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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	

<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>TRIDECETH-6</b> (UNII: 3T5PCR2H0C)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83365-003-01	56 g in 1 BOX; Type 0: Not a Combination Product	04/21/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	04/21/2023	

**Labeler** - Sichuan Gumo Brand Management Co.,Ltd (406945503)

### Establishment

Name	Address	ID/FEI	Business Operations
Sichuan Gumo Brand Management Co.,Ltd		406945503	manufacture(83365-003)

Revised: 4/2023

Sichuan Gumo Brand Management Co.,Ltd