LIDOCAINE- lidocaine spray spray Sichuan Gumo Brand Management Co.,Ltd Reference Label Set Id: f7b0ce76-8407-6d28-e053-6394a90a3d43

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.

83365-001

Active Ingredient

Lidocaine Hcl 5%

Phenylephrine HcI 0.25%

Purpose

Local Anesthetic

Vasoconstrictor

Uses

For the temporary relief of local and anorectal itching, discomfortand pain associated with anorectal disorder or anorectal inflammation.

Warnings

Do not use this product if:

pregnant or breastfeeding, ask a health professional before use. tamper-evident "Do not se this product if seal is broken or missing. you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of prostate gland unless directed by a doctor.

Do not use

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When using

When using this product do not exceed the recommended the daily usage.

certain persons can develop allergic reactions to ingredients in this product. do nut put this product into the rectum by using finger or any medical device or applicator.

If swallowed, call your Poison Control Center immediately. If condition worsens or does not improve within 7 days, consult a doctor

Stop use

Stop use and ask a doctor if

The symptom being treated does not subside, or if redness, irritation, swelling, pain, or other symptoms develop or increase.

Directions

Cleanse the affected area.

Sensitivity and possible allergy tests advised prior to use Spray sparingly to affected area after thoroughly cleansing. Wait until anesthetic effect occurs . You may reapply to continue numbing effect.

apply to the affected area up to 4 times daily.

children under 12 years of age: consult a doctor.

Other Information

Keep away from direct sunlight or heat. store in room temperature (59-86F/15-30C)

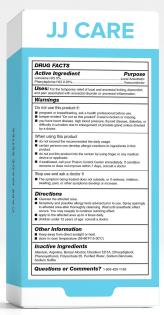
Inactive Ingredients

Allantoin, Arginline, Benzyl Alcohol, Disodium EDTA, Ethoxydiglycol, Phenoxyethanol, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Sulfite

Keep Out Of

Keep Out Of Reach Of Children If Swallowed .Get Medical Help Or Contact A Poison Control Center Right Away







LIDOCAINE

lidocaine spray spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83365-002

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			
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
ARGININE (UNII: 94ZLA3W45F)	
ALLANTOIN (UNII: 344S277G0Z)	

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:83365-002-	141 g in 1 BOX; Type 0: Not a Combination Product	03/25/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/25/2023	

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

Establishment			
Na me	Address	ID/FEI	Business Operations
Sichuan Gumo Brand Management Co.,Ltd		406945503	manufacture(83365-002)

Revised: 4/2023 Sichuan Gumo Brand Management Co.,Ltd