

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 Hcl 0.25%

Purpose

Local Anesthetic

Vasoconstrictor

Uses

For the temporary relief of local and anorectal itching , discomfort and 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 use 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

Do not use this product if :

pregnant or breastfeeding, ask a health professional before use.

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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.

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 not 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, Arginine, 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: A1A1I8X02B) | |
| ARGININE (UNII: 94ZLA3W45F) | |
| ALLANTOIN (UNII: 344S277G0Z) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83365-002-01 | 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

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

Revised: 4/2023

Sichuan Gumo Brand Management Co.,Ltd