SUNBURNT PLUS- lidocaine hydrochloride gel Quest Products, LLC.

SUN BURNT ® PLUS

Drug Facts

Active Ingredient

Lidocaine Hydrochloride 4%

Purpose

Topical Pain Relief

Uses

Temporarily relieves pain and itching due to:

- sunburn
- minor burns
- insect bites
- minor skin irritations
- minor cuts
- scrapes

Warnings

For external use only

Do not use

- in large quantities, particularly over raw surfaces or blistered areas
- if you have an allergy or hypersensitivity to any ingredients

Ask a doctor before use if

- you have severe sunburn
- you have a rash or broken or compromised skin

When using this product

Avoid contact with eyes

Stop use and ask a doctor

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean skin and apply to affected area
- adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
- children under 2 years of age: ask a doctor

Other Information

- store at 15-30°C (59-86°F)
- do not use if seal under cap is open or missing

Inactive Ingredients

Water, Hydroxyethylcellulose, Glycerin, Phenoxyethanol, Aloe Barbadensis Leaf Juice, D-Panthenol, Calunda Officinalis Extract, Echinacea Purpurea Root Extract, Mannitol, Sodium Hyaluronate, Lactobacillus Ferment, Sodium Hydroxide

PRINCIPAL DISPLAY PANEL - 118mL Tube Carton

SUNBURNT PLUS

lidocaine hydrochloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68229-601

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------------|---------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 4 a in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| LIMOSILACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP) | |
| HYDROXYETHYL CELLULOSE (5500 MPA.S AT 2%) (UNII: M825OX60H9) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| WATER (UNII: 059QF0KO0R) | |
| CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD) | |
| PANTHENOL (UNII: WV9CM0067Z) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |

ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)

GLYCERIN (UNII: PDC6A3C0OX)

MANNITOL (UNII: 30WL53L36A)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68229-601-02 | 1 in 1 CARTON | 02/23/2024 | |
| 1 | NDC:68229-601-01 | 118 mL 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 Drug | M017 | 02/23/2024 | |

Labeler - Quest Products, LLC. (075402441)

| Establishment | | | | |
|---------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Fill Tech USA | | 926433855 | manufacture(68229-601) | |

Revised: 2/2024 Quest Products, LLC.