**ADVANCED SEAL BARRIER PLUS PAIN RELIEF- lidocaine spray**
**Kericure Inc.**

*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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**ADVANCED SEAL® BARRIER + PAIN RELIEF**

**DRUG FACTS**

**Active Ingredients:**

Lidocaine 2%

**Purpose:**

Topical anesthetic

**Uses:** For the temporary relief of pain and itch in minor cuts, burns, scrapes, skin irritations, insect bites and sunburn

**Warnings:** For external use only. Avoid contact with eyes. Do not ingest. Contact a doctor if pregnant, breastfeeding, or if condition worsens.

Keep out of reach of children.

**Directions:** Adults & children age 2 & older. Shake well then apply spray. **DO NOT RUB IN.** Allow a clear, thin film to set. Apply up to 3x a day for 7 days. Children under 2 years of age consult a physician

**Inactive Ingredients:** Purified water, ethanol, polyacrylate polymer, cellulose

**Soothe, Seal & Protect™**

**Lidocaine + breathable, elastic barrier**

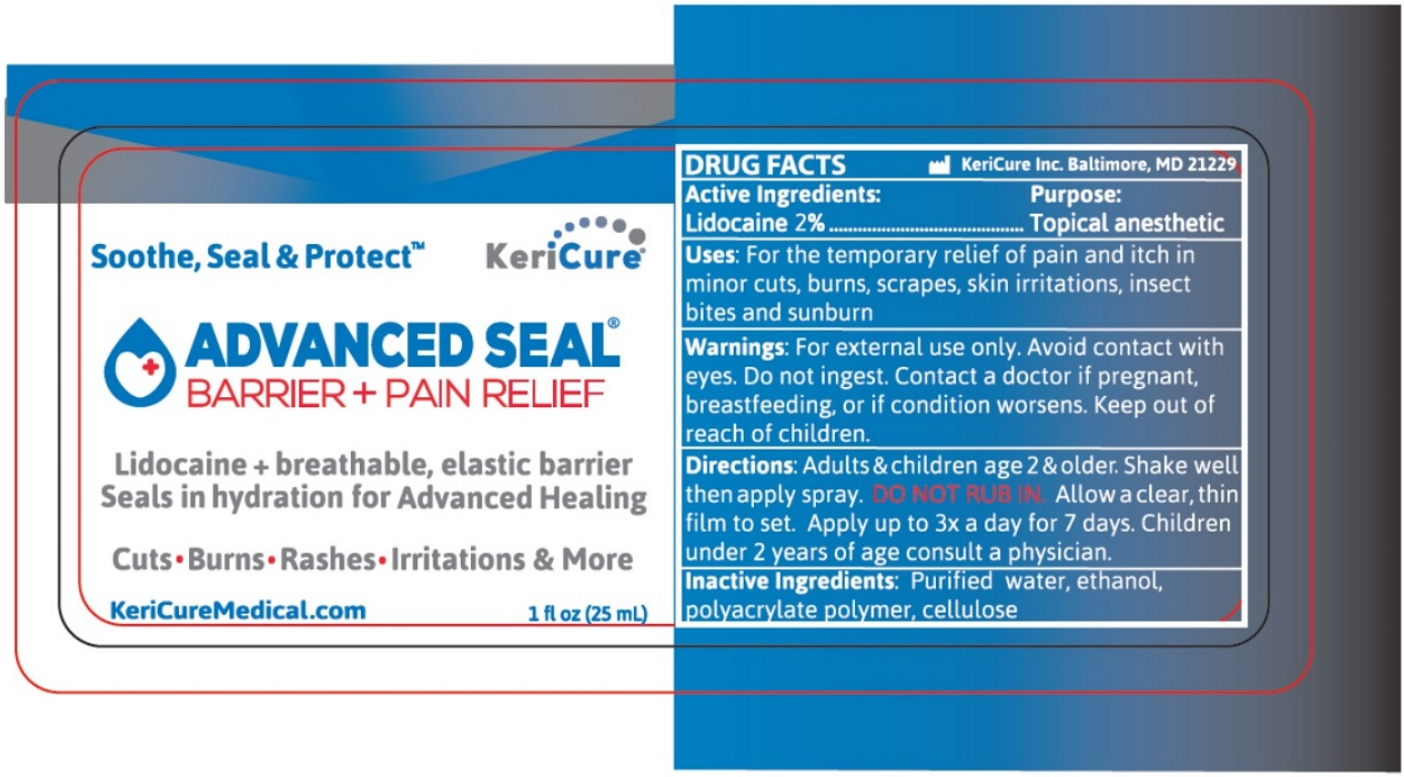
**Seals in hydration for Advanced Healing**

**Cuts • Burns • Rashes • Irritation & More**

**KeriCureMedical.com**

**KeriCure Inc. Baltimore, MD 21229**

**Packaging**




# ADVANCED SEAL BARRIER PLUS PAIN RELIEF

lidocaine spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:78280-703 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **LIDOCAINE** (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 20 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)** (UNII: JZ1374NL9E) | |
| **HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)** (UNII: S38J6RZN16) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:78280-703-01 | 25 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 04/10/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 04/10/2020 | |

## Labeler - Kericure Inc. (966638681)

Revised: 5/2020 Kericure Inc.