

SIMPLICITY DESENSITIZING- lidocaine gel

Simplicity Laser, LLC

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.

Simplicity Desensitizing Gel

Active Ingredient:

Lidocaine 4% w/w

Purpose

Topical anesthetic

Use:

temporarily relieves pain and itching due to:

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

Warnings:

For external use only.

- do not use in or near the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask doctor if

- Allergic reaction occurs
- Condition worsens or does not improve within 7 days
- Symptoms clear up and return within a few days
- Redness, irritation, swelling, pain or other symptoms begin or increase

Keep out of reach of children.

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

Directions:

- Adults and children 2 years and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years of age: Consult a doctor.

Other Information

Store at USP controlled room temperature 20-25 deg.C (68-77 deg.F).

Inactive ingredients

Ag, carbomer 940, deionized water

Simplicity Desensitizing Gel, 1 fl oz/30mL (69109-004-30)

simplicity
**Desensitizing
Gel**

Topical Anesthetic Gel

Lidocaine 4%

NDC #

1 fl oz | 30ml

simplicity

DISTRIBUTED BY:
SIMPLICITY LASER, LLC
LINDON, UT 84042
SIMPLICITYLASER.COM - 800 559 9138



DRUG FACTS

Active ingredient

Lidocaine 4% w/w..... Topical anesthetic

Purpose

Use

Temporarily relieves pain and itching due to: minor cuts, minor scrapes, sunburn, minor burns, minor skin irritations and insect bites.

Warnings

For external use only • Do not use in or near the eyes • Do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if

Allergic reaction occurs • Condition worsens or does not improve within 7 days • Symptoms clear up and return within a few days • Redness, irritation, swelling, pain or other symptoms begin or increase.

DRUG FACTS (continued)

Keep out of reach of children

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

Directions

- Adults and children 2 years and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years of age: Consult a doctor.

Other information

- Store at USP controlled room temperature 20°-25°C (68° - 77°F).

Inactive ingredients

Ag, carbomer 940, deionized water.

Questions?

Call: 1 800 559 9138

SIMPLICITY DESENSITIZING

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69109-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69109-004-30	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/15/2014	

Labeler - Simplicity Laser, LLC (079456595)

Establishment

Name	Address	ID/FEI	Business Operations
Results RNA, LLC		078395000	manufacture(69109-004)

Revised: 7/2014

Simplicity Laser, LLC