

INSTANT COOL SKIN INSTANT RELIEF. SUDDEN RESULTS- lidocaine 0.5% lotion
Therapon Skin Health, LP

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.

Active Ingredients

Lidocaine 0.5%

Uses

External Analgesic

Indications

For temporary relief of pain associated with sunburn and minor skin burns.

Warnings

For external use only, avoid contact with eyes. Do not use in large quantities, particularly over raw surfaces or blistered surfaces

Keep out of reach of children.

Stop use and ask a doctor if:

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Directions

- Adults and children 2 years and older: apply to affected area. Do not use more than 3-4x daily. Repeat daily until healed.
- Children under 2 years of age: consult a doctor

Inactive Ingredients

Water, Ethanol, Propylene Glycol, Lactic Acid

Package Display

INSTANT COOL SKIN

Directions:

Cover burned skin area with Instant Cool Skin. Gently spread over burn surface. Do not use more than 3-4x daily. Repeat daily until healed.

INSTANT COOL SKIN

INSTANT RELIEF. SUDDEN RESULTS



PAIN RELIEVING LOTION FOR TEMPORARY RELIEF OF BURNS



THERMAL

RELIEF FROM:

- Severe Sunburns
- Thermal Burns
- Hot Grease Splashes



SUNBURN

CLINICAL FORMULA:

- Reduces pain
- Fast action



1ST/2ND DEGREE BURNS

INSTANT COOL SKIN

Instant Relief for:

Environmental Burns:
Sunburns and wind burns

Household Burns:
Curling iron burns, steam burns, grill burns, hot grease burns and stove burns

Work-related Burns:
Grill burns, hot grease burns, welding burns, beauty shop burns and steam burns

Additional Uses:
Provides relief from insect bites

INSTANT COOL SKIN

External pain relieving lotion for the temporary relief of pain and itching from burns, sunburn and insect bites.

Drug Facts

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Questions? 844-419-4138
www.instantcoolskin.com

dist. by Sudden Results, LLC
Springdale, AR 72764
Made in the USA



UPC

net wt 2oz

INSTANT COOL SKIN INSTANT RELIEF. SUDDEN RESULTS

lidocaine 0.5% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66428-007
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 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LACTIC ACID (UNII: 33X04XA5AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66428-007-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/15/2015	

Labeler - Therapon Skin Health, LP (792518995)

Revised: 6/2015

Therapon Skin Health, LP