DCH BURN RELIEF- lidocaine hcl gel
Derma Care Research Labs, 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.

DCH Burn Relief Gel, Lidocaine HCl 0.5%

Lidocaine HCl 0.5%

External Analgesic.

For the temporary relief of pain and itching due to sunburn, minor burns, insect bites, minor cuts, scrapes, and minor skin irritations.

For external use only.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

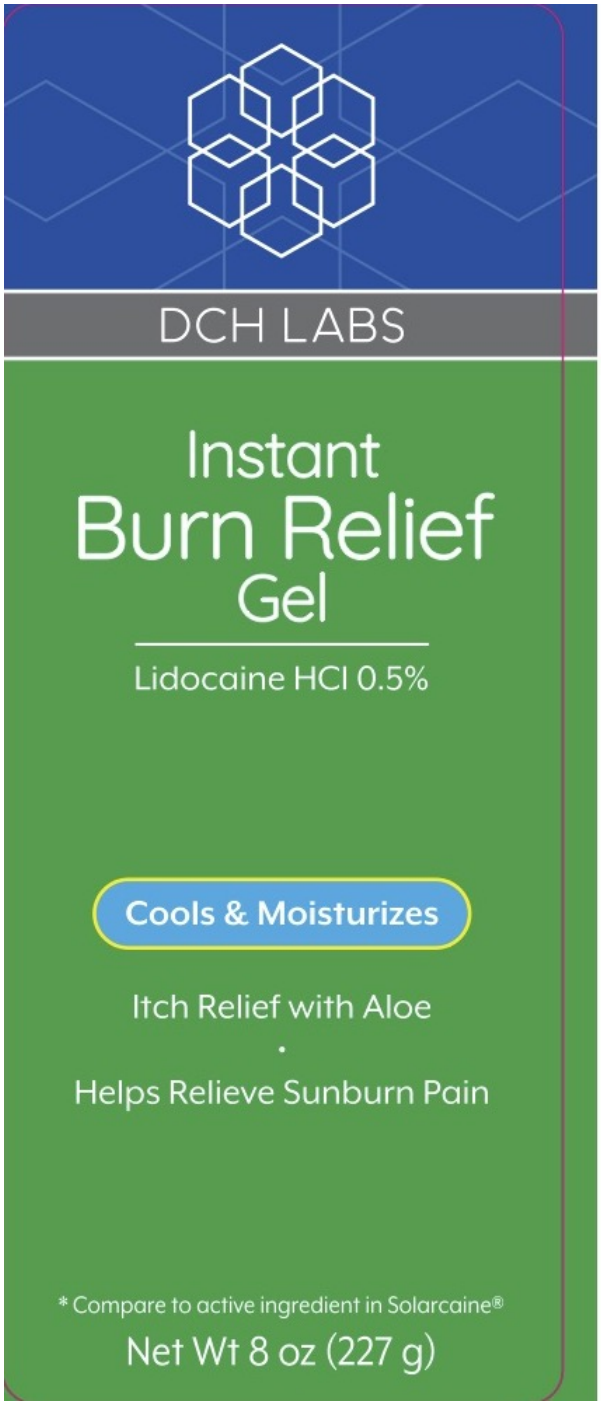
When using this product avoid contact with eyes. Rinse with water if contact occurs.

Stop use and ask a doctor if the condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If the product is swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 2 years and older: apply to the affected area, not more than 3 to 4 times a day. Children under 2 years of age: consult a physician. To apply to face, squeeze into palm of hand and gently apply.

Water, Glycerin, Isopropyl Alcohol, Aloe Barbadensis Leaf Extract, Menthol, Propylene Glycol, Polysorbate 80, Triethanolamine, Carbomer, Disodium EDTA, Blue 1, Yellow 5, Diazolidinyl Urea.



Drug Facts

Active ingredient — **Purpose**

Lidocaine Hydrochloride 0.5% ..... External Analgesic

Uses For the temporary relief of pain and itching associated with • sunburn • minor burns • minor cuts • scrapes • insect bites • minor skin irritations.

Warnings

For external use only.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

When using this product avoid contact with eyes. Rinse with water if contact occurs.

Stop use and ask a doctor if • symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • adults and children 2 years or older: apply to affected area not more than 3 to 4 times daily • children under 2 years of age: ask a doctor • to apply to face, squeeze into palm of hand and gently apply.

Inactive ingredients Water, Glycerin, Isopropyl Alcohol, Aloe Barbadensis Leaf Extract, Menthol, Propylene Glycol, Polysorbate 80, Triethanolamine, Carbomer, Disodium EDTA, Blue 1, Yellow 5, Diazolidinyl Urea.

*This product is not manufactured or distributed by Bayer®, owner of the registered trademark Solarcaine®

Manufactured by:
DermaCare Research Labs, LLC
440 Fentress Blvd., Daytona Beach, FL 32114

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DCH BURN RELIEF

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72839-955
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE -	LIDOCAINE HYDROCHLORIDE	0.5 g

UNII:98PI200987)	ANHYDROUS	in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-955-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/11/2021	

Labeler - Derma Care Research Labs, LLC (116817470)

Revised: 6/2023 Derma Care Research Labs, LLC