

SUNBURN PAIN RELIEVER CVS- lidocaine hydrochloride 0.5% gel CVS

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.

Drug Facts

Active ingredient

Lidocaine Hydrochloride 0.5%

Purpose

Pain Reliever

Uses for temporary relief of pain and itching due to

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

Warnings

For external use only

When using this product

- avoid contact with eyes. Rinse with water if contact occurs.

Stop use and ask a doctor if

- symptoms last more than 7 days.

Keep out of reach of the children

Directions

- adults and children 2 years of age and older: apply to affected area, not more than 3 to 4 times a day
- children under 2 years of age: consult a physician

Inactive ingredients

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



Compare to the active ingredient in Solarcaine® Burn Relief Gel*

Burn Relief Gel

WITH LIDOCAINE HCl 0.5%

Restores moisture

- Soothes & relieves
- Cooling sunburn relief
- Topical analgesic gel



NET WT
8 OZ (226 g)

Drug Facts

Active ingredient	Purpose
Lidocaine Hydrochloride 0.5%	Pain Reliever

Uses For the temporary relief of pain and itching due to
 • sunburn • minor burns • insect bites • minor cuts • scrapes

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

Directions • Adults and children 2 years and older: apply to affected area not more than 3 - 4 times a day.
 • Children under 2 years of age: consult a physician.

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

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

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REPRESENTS CLEAR SUBSTRATE
- DOES NOT PRINT -

SUNBURN PAIN RELIEVER CVS

lidocaine hydrochloride 0.5% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-840
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Alcohol (UNII: ND2M416302)	
Menthol (UNII: L7T10EIP3A)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Propylene Glycol (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-840-06	226 g in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/18/2017	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(69842-840) , label(69842-840)

Revised: 11/2017

CVS