

SUNBURN PAIN RELIEF- lidocaine hydrochloride 0.5% gel

Top Care

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

External analgesic

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

LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)				
Diazolidinyl Urea (UNII: H5RIZ3MPW4)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
Glycerin (UNII: PDC6A3C0OX)				
Isopropyl Alcohol (UNII: ND2M416302)				
Menthol (UNII: L7T10EIP3A)				
Polysorbate 80 (UNII: 6OZP39ZG8H)				
Propylene Glycol (UNII: 6DC9Q167V3)				
TROLAMINE (UNII: 9O3K93S3TK)				
Water (UNII: 059QF0KO0R)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-883-06	1 in 1 CARTON	02/12/2016	
1		237 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	02/12/2016		

Labeler - Top Care (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-883) , label(36800-883)