SIGNATURE CARE ALOE VERA GEL WITH LIDOCAINE- lidocaine gel Safeway, Inc.

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.

Safeway Signature Care Aloe Vera Gel with Lidocaine

Active ingredient

Lidocaine 0.8% (as Lidocaine HCI)

Purpose

External Analgesic

Uses

For the temporary relief of pain and itching associated with sunburn, minor burns, minor cuts, scrapes, insect bites, and 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. If contact occurs, rinse with water to remove.

Stop use and ask a doctor if

• condition worsens • symptoms persist for more than 7 days • symptoms clear up and occur again within a few days

Keep out of reach of children

If swallowed, seek medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: Ask a doctor.

Inactive ingredients

water, aloe barbadensis leaf juice, SD alcohol 40-B, propylene glycol, laureth-23, polysorbate 20, glycerin, allantoin, tocopheryl acetate (vitamin E acetate), retinyl palmitate (vitamin A palmitate) tocopherol, carbomer, triethanolamine, menthyl lactate, diazolidinyl urea, disodium EDTA, menthol, fragrance, aleurites moluccanus seed extract, carica papaya (papaya) fruit extract, colocasia antiquorum root extract, mangifera indica (mango) fruit extract, passiflora incarnata flower extract, plumeria acutifolia flower extract, psidium guajava fruit extract, fragrance, blue 1, yellow 5.



Signature Care" cares about your health and wellness from the outside in. Aloe Vera Gel with Lidocaine takes the "ouch" out of sunburned skin with cooling relief. The gentle moisturizers hydrate skin on contact to restore its balance. Lidocaine brings fast relief to painful skin irritations like sunburn, minor burns, cuts and insect bites.

Drug Facts

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Other information May stain some fabrics,

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Questions? Call 1-888-723-3929

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*Plus stabilizers and preservatives to ensure stability and efficacy.





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SIGNATURE CARE ALOE VERA GEL WITH LIDOCAINE

lidocaine gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:21130-733

Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	8 mg in 1 g			

Inactive Ingredients				
Ingredient Name	Strength			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
MANGO (UNII: 162913NR86)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
LAURETH-23 (UNII: N72LMW566G)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
ALLANTOIN (UNII: 344S277G0Z)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
TROLAMINE (UNII: 903K93S3TK)				
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
LEVOMENTHOL (UNII: BZ1R15MTK7)				
KUKUI NUT OIL (UNII: TP11QR7B8R)				
PAPAYA (UNII: KU94FIY6JB)				
COLOCASIA ESCULENTA ROOT (UNII: H7B71Q0G0D)				
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z)				
GUAVA (UNII: 74070D6VG0)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
WATER (UNII: 059QF0KO0R)				
PLUMERIA ALBA FLOWER OIL (UNII: T69Z2432CU)				

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:21130-733- 68	454 g in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2011			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	12/14/2011		

Labeler - Safeway, Inc. (009137209)

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