WEGMANS ALOE AFTER SUN GEL WITH LIDOCAINE HCL EXTERNAL ANALGESIClidocaine hydrochloride gel WEGMANS FOOD MARKETS 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.

Wegmans Aloe After Sun Gel with Lidocaine HCl External Analgesic

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, laureth-23, polysorbate 20, glycerin, allantoin, carbomer, triethanolamine, menthyl lactate, 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, tocopheryl acetate (vitamin E acetate), tocopherol, phenoxyethanol, benzyl alcohol, fragrance

Label



WEGMANS ALOE AFTER SUN GEL WITH LIDOCAINE HCL EXTERNAL ANALGESIC lidocaine hydrochloride gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) 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
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MANGO (UNII: 162913NR86)	
ALCOHOL (UNII: 3K9958V90M)	
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)	
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
PLUMERIA ALBA FLOWER OIL (UNII: T69Z2432CU)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:47124-129- 68	454 g in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	02/06/2019		