EQUATE SUNBURN RELIEF WITH ALOE AFTER SUN- lidocaine gel
Wal-Mart Stores 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.

Equate Sunburn Relief with Aloe After Sun Gel

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, alcohol denat., propylene glycol, laureth-23, glycerin, polysorbate 20, allantoin, carbomer, triethanolamine, menthyl lactate, disodium EDTA, menthol, 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, tocopherol, phenoxyethanol, benzyl alcohol, fragrance, blue 1, yellow 5.

Equate Sunburn Relief with Aloe After Sun Gel

EQUATE SUNBURN RELIEF WITH ALOE AFTER SUN

lidocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-788
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
MANGO (UNII: I629I3NR86)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LAURETH-23 (UNII: N72LMW566G)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALLANTOIN (UNII: 344S277G0Z)	
CARBOMER 934 (UNII: Z135WT9208)	
TROLAMINE (UNII: 9O3K93S3TK)	
MENTHYL D-LACTATE, (-)- (UNII: XFS8QYW6WY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL (UNII: L7T10EIP3A)	
ALEURITES MOLUCCANA SEED (UNII: J87WJ3E7VW)	
CARICA PAPAYA WHOLE (UNII: S0U63B0Q51)	
COLOCASIA ESCULENTA ROOT (UNII: H7B71Q0G0D)	
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z)	
PSIDIUM GUAJAVA LEAF (UNII: PM0F263X0Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PIGMENT BLUE 1 (UNII: 4SBE571RQF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49035-788-20	567 g in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/18/2019	

Labeler - Wal-Mart Stores Inc (051957769)

Registrant - FRUIT OF THE EARTH, INC. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(49035-788)

Revised: 12/2019

Wal-Mart Stores Inc