

ALOE VERA GEL- lidocaine hcl, menthol gel

Amazon

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.

Solim0 747.001 747AB

Active ingredient

Lidocaine HCl 0.7%

Menthol 0.2%

Purpose

topical analgesic

Uses

for the temporary relief of pain and itching associated with

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

Warnings

For external use only

When using this product

avoid contact with the eyes

do not use

in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

condition worsens, or 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 swallowed, get medical help or contact a Poison Control Center right away

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, alcohol denat., polysorbate 20, glycerin, Aloe barbadensis leaf juice, carbomer, benzophenone-4, triethanolamine, benzyl alcohol, phenoxyethanol, blue 1

Adverse Reactions Section

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principal display panel

SOLIMO

After Sun Gel

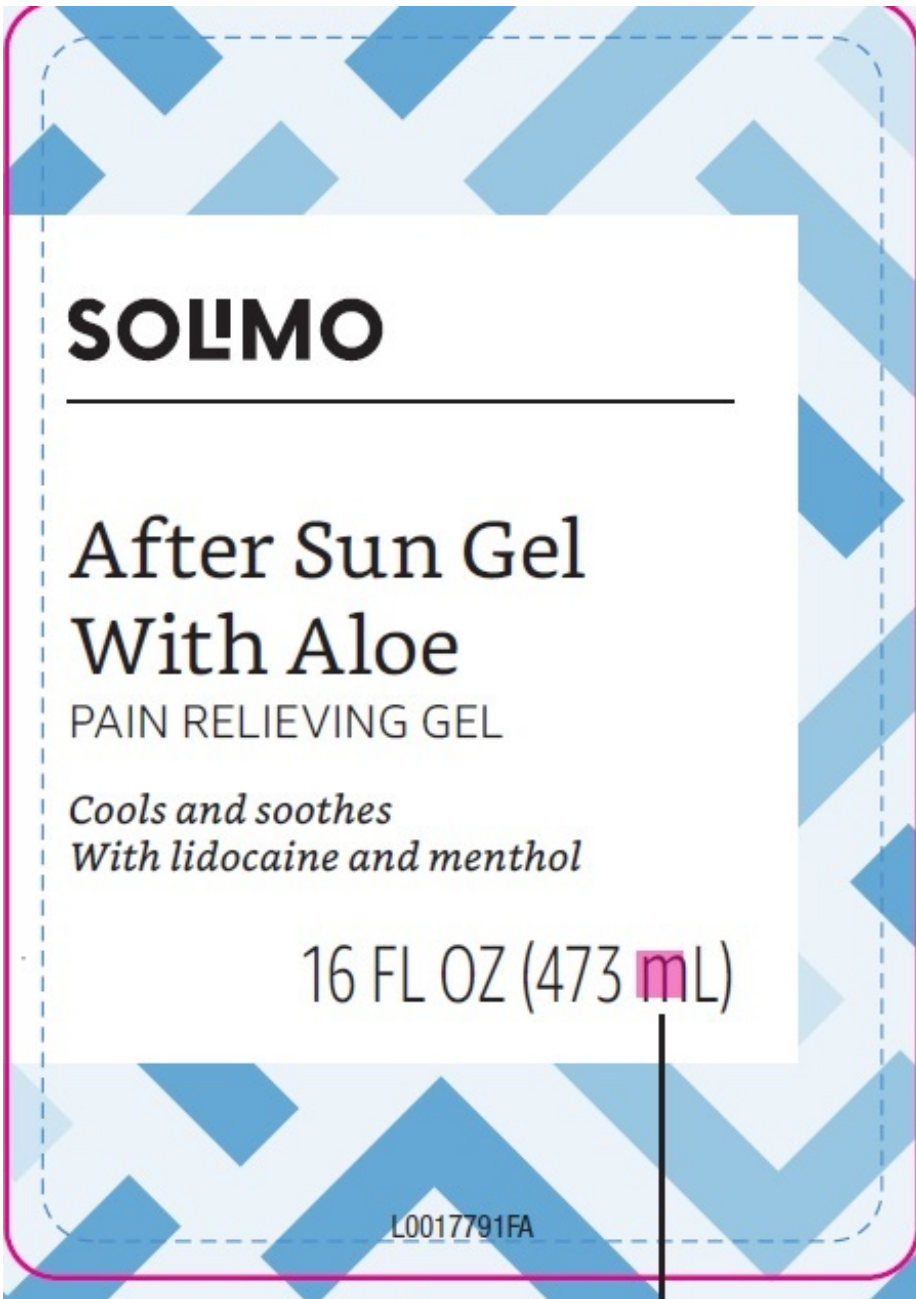
With Aloe

PAIN RELIEVING GEL

Cools and Soothes

With lidocaine and menthol

16 FL OZ (473 mL)



ALOE VERA GEL

lidocaine hcl, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-747
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4.97 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
SULISOBENZONE (UNII: 1W6L629B4K)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-747-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/17/2018	

Labeler - Amazon (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-747)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72288-747)