FRUIT OF THE EARTH COOL BLUE ALOE VERA COOLING- menthol gel Fruit of the Earth, 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.

Fruit of the Earth Cool Blue Aloe Vera Gel with Menthol

Active Ingredients

Menthol 0.5%

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

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.

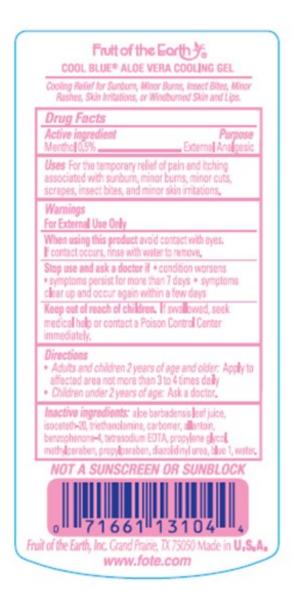
Directions

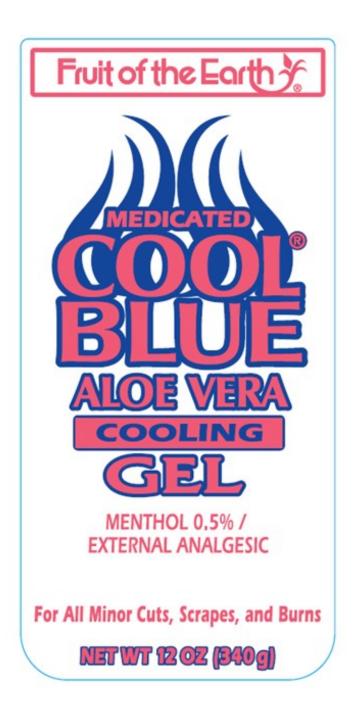
- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: Ask a doctor.

Inactive Ingredients:

aloe barbadensis leaf juice, isoceteth-20, triethanolamine, carbomer, allantoin, benzophenone-4, tetrasodium EDTA, propylene glycol, methylparaben, propylparaben, diazolidinyl urea, blue 1, water.







Fruit of the Earth % COOL BLUE® ALOE VERA COOLING GEL

Cooling Relief for Sunburn, Minor Burns, Insect Bites, Minor Rashes, Skin Irritations, or Windburned Skin and Lips.

Drug Facts

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NOT A SUNSCREEN OR SUNBLOCK



Fruit of the Earth, Inc. Grand Prairie, TX 75050 www.fote.com

FRUIT OF THE EARTH COOL BLUE ALOE VERA COOLING

menthol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62217-080

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	- 10 and 11 g. 0 and 11 g. 10 and 1					
	Ingredient Name	Basis of Strength	Strength			
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 1 g			

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ISOCETETH-20 (UNII: O020065R7Z)				
TROLAMINE (UNII: 903K93S3TK)				
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
SULISOBENZONE (UNII: 1W6L629B4K)				
EDETATE SODIUM (UNII: MP1J8420LU)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
ALLANTOIN (UNII: 344S277G0Z)				
WATER (UNII: 059QF0KO0R)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:62217-080- 33	113 g in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2013			
2	NDC:62217-080- 34	340 g in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2013			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	09/30/2013			
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Labeler - Fruit of the Earth, Inc. (079559467)

Revised: 7/2021 Fruit of the Earth, Inc.