

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 

MEDICATED
Fast Burn Relief

COOL BLUE[®]
ALOE VERA
COOLING
GEL

MENTHOL 0.5% /
EXTERNAL ANALGESIC

For All Minor Cuts, Scrapes, and Burns

NET WT 4 OZ (113g)

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



0 71661 13104 4

Fruit of the Earth, Inc. Grand Prairie, TX 75050 Made in U.S.A.
www.fote.com

Fruit of the Earth 

MEDICATED
COOL BLUE®
ALOE VERA
COOLING
GEL

MENTHOL 0.5% /
 EXTERNAL ANALGESIC

For All Minor Cuts, Scrapes, and Burns

NET WT 12 OZ (340g)

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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

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: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	

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	

Labeler - Fruit of the Earth, Inc. (079559467)

Revised: 7/2021

Fruit of the Earth, Inc.