

FRUIT OF THE EARTH ALOE VERA COOL BLUE- lidocaine hydrochloride 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 Aloe Vera Cool Blue Gel

Active Ingredients

Lidocaine 1.0% (as Lidocaine HCl)

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.

Other Information: May stain some fabrics.

Inactive Ingredients

Aloe Barbadosis Leaf Juice, Isoceteth-20, Triethanolamine, Carbomer, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Benzophenone-4, Blue 1.

Fruit of the Earth

Aloe Vera

Cool Blue Gel

567 grams

NDC: 62217-200-20



ALOE VERA




COOL BLUE[®] GEL

Lidocaine Topical Analgesic Gel

COOLING PAIN RELIEF

NET WT **2.0** OZ (56.7 g)

Fruit of the Earth[®]

ALOE VERA COOL BLUE[®] GEL

An effective gel combining the cooling, soothing and protective properties of Aloe Vera and the anesthetic action of Lidocaine. Provides cooling relief for sunburn, minor burns, insect bites, skin irritations, or windburned skin and lips.

Drug Facts	
Active ingredient	Purpose
Lidocaine 1% (as Lidocaine HCl)	External Anesthetic
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	
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Fruit of the Earth, Inc.
Grand Prairie, TX 75050

At Fruit of the Earth
we pride ourselves in being 100%
American owned and operated.

www.fote.com



FRUIT OF THE EARTH ALOE VERA COOL BLUE

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISO CETETH-20 (UNII: O020065R7Z)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
EDETATE SODIUM (UNII: MP1J8420LU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SULISOBENZONE (UNII: 1W6L629B4K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-200-20	567 g in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/10/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(62217-200)

Revised: 12/2017

Fruit of the Earth, Inc.