

**ORAL DENT FRESH MINT- eucalyptol, thymol, methyl salicylate , menthol mouthwash
International Cosmetics Ltd.**

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.

Oral Dent Fresh Mint

Active ingredients (W/V)

Eucalyptol 0.092%
Thymol 0.064%
Methyl Salicylate 0.060%
Menthol 0.042%

Purpose

Antiplateque/Antigingivitis

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

Helps kill germs that cause plaque, gingivitis and bad breath.

Warnings

- Do not swallow
- Not to be used by children under 12 years of age

Directions

Rinse Full Strength with 2/3 ounce (20 ml) for 30 seconds twice a day to help kill germs that cause bad breath, plaque and gingivitis.

Other information

- Cold temperature may cloud this product; its efficacy will not be affected. Store at room temperature (59⁰-86⁰ F)
- Do not use if security band around cap is missing or broken

Inactive ingredients

Water, Alcohol 15%, Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavour, Sodium Saccharin, Sodium Citrate, Citric Acid, FD&C Green No.3.


Manufactured by

International Cosmetics Ltd.

ICL Drive, Bhagowtie Trace,
 San Juan, Trinidad & Tobago, W.I.
 INFO. CALL:1-868-675-2674

Packaging



Drug facts ORAL-DENT® Fresh-Mint	
Active Ingredients (w/v) Eucalyptol 0.092%, Thymol 0.064%, Methyl Salicylate 0.060%, Menthol 0.042%	Purpose Antiplaque/Antigingivitis
Uses ■ Helps kill germs that cause plaque, gingivitis, and bad breath.	
Warnings ■ Keep out of reach of children. ■ Do not swallow. ■ Not to be used by children under 12 years of age. ■ In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions: Rinse Full Strength with 2/3 ounce (20ml) for 30 seconds twice a day to help kill germs that cause bad breath, plaque and gingivitis.	
Other Information ■ Cold temperatures may cloud this product; its efficacy will not be affected. Store at room temperature (59°-86°F) ■ Do not use if security band around cap is missing or broken.	
Inactive Ingredients: Water, Alcohol 21.6%, Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavor, Sodium Saccharin, Sodium Citrate, Citric Acid, and FD&C Green #3	
Manufactured by: International Cosmetics Ltd. ICL Drive, Bhagowtie Trace, San Juan, Trinidad & Tobago,W.I. INFO. CALL: 1-868-675-2674 NDC-66969-6021-1	
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ORAL DENT FRESH MINT			
eucalyptol, thymol, methyl salicylate , menthol mouthwash			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66969-6021
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.092 g in 100 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.064 g in 100 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.060 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.042 g in 100 mL	
Inactive Ingredients			

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66969-6021-1	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/10/2013	

Labeler - International Cosmetics Ltd. (857266290)

Establishment

Name	Address	ID/FEI	Business Operations
International Cosmetics Ltd.		857266290	manufacture(66969-6021)

Revised: 3/2014

International Cosmetics Ltd.