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

Antiplaque/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

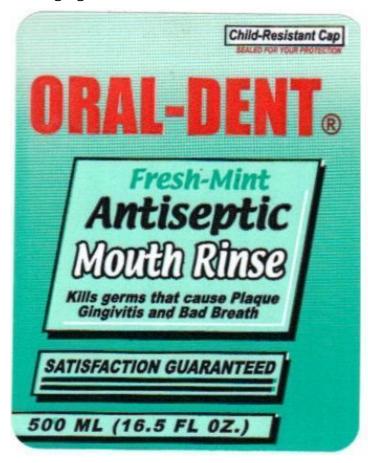
Water, Alcohol 15%, Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavour, Sodium Saccharin, Sodium Citrate, Citric Acid, FD&C Green No.3.

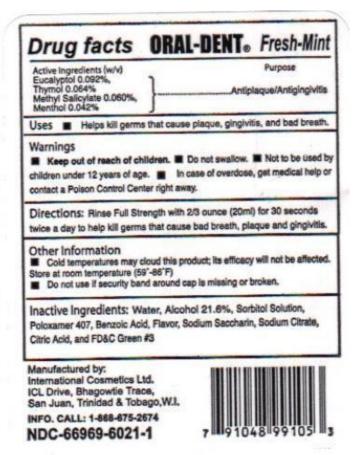
Manufactured by

International Cosmetics Ltd.

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

Packaging





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: 8 SKN0 B0 MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM) SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY) SO DIUM CITRATE (UNII: 1Q73Q2JULR) CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

P	ackaging			
#	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	0 1/10/20 13	

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.