

**ORAL DENT AMBER- 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.*

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**Oral Dent Amber**

***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 (59<sup>0</sup>-86<sup>0</sup> F)
- Do not use if security band around cap is missing or broken.

***Inactive ingredients***

Water, Alcohol 20%, Benzoic Acid, Poloxamer 407, Sodium Benzoate and Caramel.

Manufactured by

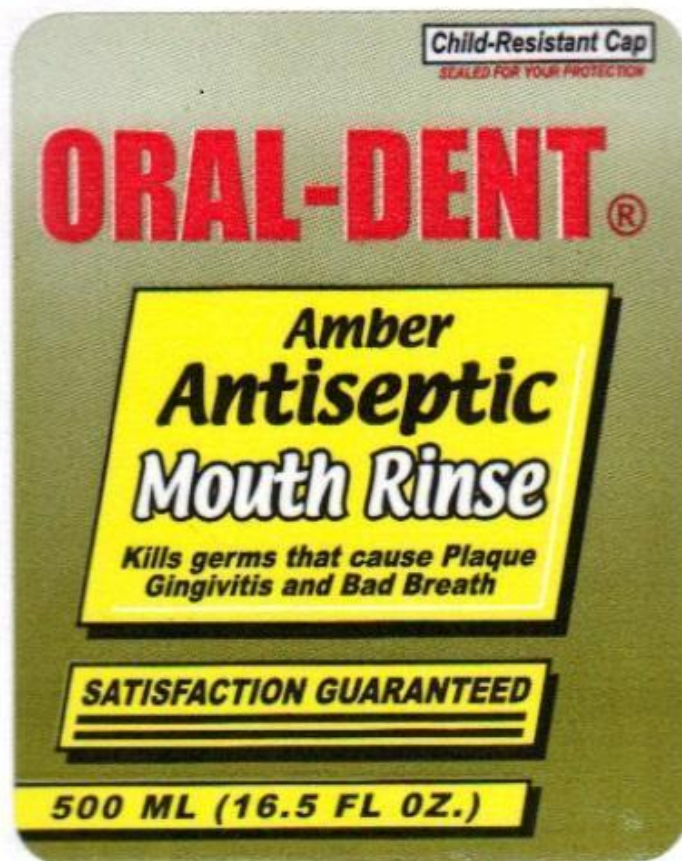
International Cosmetics Ltd.

ICL Drive, Bhagowtie Trace,

San Juan, Trinidad & Tobago, W.I.

INFO. CALL:1-868-675-2674

**Packaging**



<b>Drug facts ORAL-DENT® Amber</b>	
Active Ingredients (w/v) Eucalyptol 0.092%, Thymol 0.064%, Methyl Salicylate 0.060%, Menthol 0.042%	Purpose Antiplaque/Antigingivitis
<b>Uses</b> ■ Helps kill germs that cause plaque, gingivitis, and bad breath.	
<b>Warnings</b> ■ 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.	
<b>Directions:</b> 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.	
<b>Other Information</b> ■ 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.	
<b>Inactive Ingredients:</b> Water, Alcohol 26.9%, Benzoic Acid, Poloxamer 407, Sodium Benzoate and Caramel.	

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International Cosmetics Ltd.  
ICL Drive, Bhagowtie Trace,  
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INFO. CALL: 1-868-675-2674  
NDC-66969-6020-0



**ORAL DENT AMBER**

eucalyptol, thymol, methyl salicylate, menthol mouthwash

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66969-6020
<b>Route of Administration</b>	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: 059QF0K00R)	

ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CARAMEL	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66969-6020-0	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(66969-6020)