

ORAL DENT AMBER- eucalyptol ,thymol, methyl salicylate, menthol mouthwash
International Cosmetic Limited

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 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 (59⁰-86⁰ 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 for

International Cosmetics Ltd.

ICL Drive, Bhagowtie Trace,

San Juan, Trinidad & Tobago, W.I.

INFO. CALL:1-868-675-2674

Packaging

Drug facts ORAL-DENT® Amber

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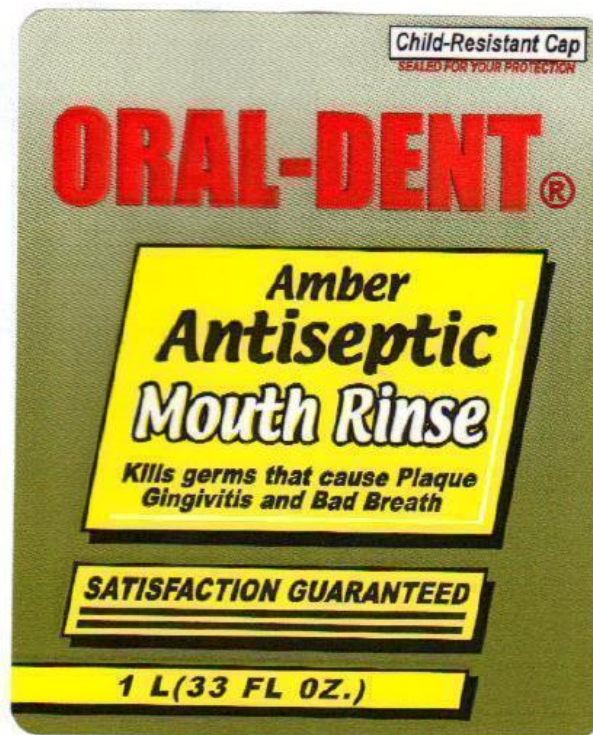
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 NDC-66969-6012-2

EXPORT



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ORAL DENT AMBER

eucalyptol ,thymol, methyl salicylate, menthol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66969-6012
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: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	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)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

POLO XAMER 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:66969-6012-2	1000 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 Cosmetic Limited (857266290)

Establishment

Name	Address	ID/FEI	Business Operations
International Cosmetics Ltd.		857266290	manufacture(66969-6012)

Revised: 3/2014

International Cosmetic Limited