

ORAL DENT CITRUS- 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 Citrus

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

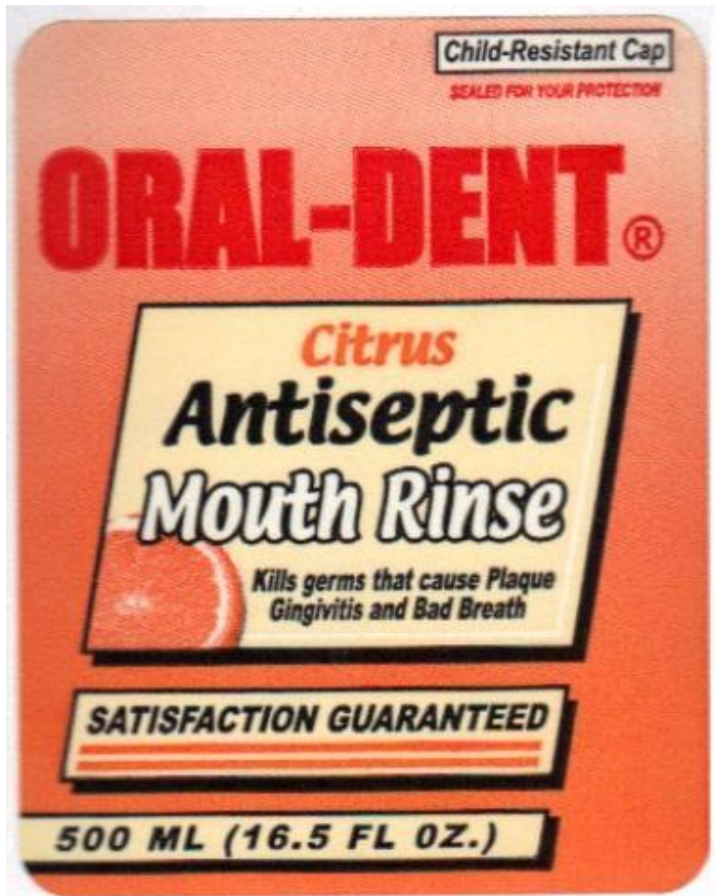
Water, Alcohol (15%), Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavour, Sodium Saccharin, Sodium Citrate, Citric Acid, FD&C Yellow No.6, FD&C Red No. 40.

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® Citrus

Active Ingredients (w/v) Eucalyptol 0.092%, Thymol 0.064%, Methyl Salicylate 0.060%, Menthol 0.042%	PurposeAntiplaque/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, FD&C Orange.	

Manufactured by:
 International Cosmetics Ltd.
 ICL Drive, Bhagowtie Trace,
 San Juan, Trinidad & Tobago, W.I.
 INFO. CALL: 1-868-675-2674
 NDC-66969-6023-3

ORAL DENT CITRUS

eucalyptol, thymol, methyl salicylate, menthol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66969-6023
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 YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66969-6023-3	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(66969-6023)

Revised: 3/2014

International Cosmetics Ltd.