

BUENOS DIAS DE PERSONNA COOL MINT- eucalyptol, menthol, methyl salicylate, thymol 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.

Buenos Dias de Personna cool mint

Active ingredients (W/V)

Eucalyptol 0.092%

Menthol 0.042%

Methyl Salicylate 0.060%

Thymol 0.064%

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 21.6%, Sorbitol Solution, Poloxamer 407, Benzoic Acid, Sodim Benzoate ,Flavour, Sodium Saccharin and FD&C Green No.3.

Distributed By

2011 Energiser Personal Care LL
 dba Personna International of PR
 #36 Carr 20 Kim 2.2 Suite 203, Guaynabo PR00966
 787-761-9500
 Made in Trinidad & Tobago, W.I.

Packaging

Drug facts		cool mint
Active Ingredients (w/v)		Purpose
Eucalyptol 0.092%	}	Antiplaque Antigingivitis
Menthol 0.042%		
Methyl Salicylate 0.060%		
Thymol 0.064%		
Use Help kill germs that cause plaque, gingivitis, and bad breath.		
Warnings: Keep out of reach of children.		
<ul style="list-style-type: none"> 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.		
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<small>© 2011 Energizer Personal Care LLC dba Personna International of PR #36 Carr 20 Kim 2.2 Suite 203, Guaynabo, PR 00966 787-761-9500 Made in Trinidad & Tobago, W.I. NDC-66969-6003-3</small>		



BUENOS DIAS DE PERSONNA COOL MINT

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66969-6003
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.042 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.060 g in 100 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.064 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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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:66969-6003-3	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 Cosmetics Ltd. (857266290)

Establishment

Name	Address	ID/FEI	Business Operations
International Cosmetics Ltd.		857266290	manufacture(66969-6003)

Revised: 3/2014

International Cosmetics Ltd.