

ANTISEPTIC - eucalyptol mouthwash

Onpoint, Inc

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.

Drug Facts

Active ingredients

Eucalyptol 0.092% Menthol 0.024%
Methyl salicylate 0.060% thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use helps control plaque that leads to gingivitis

Warnings

Do not use if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. see your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if gingivitis, bleeding, or redness persists for more than 2 weeks.

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow
children under 12 years of age - consult a dentist or doctor
•this rinse is not intended to replace brushing or flossing

Other information cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F).

Inactive ingredients water, alcohol (21.6%), sorbitol solution, flavoring, PEG-40 hydrogenated castor oil, poloxamer 407, benzoic acid, zinc chloride, sucralose and/or sodium saccharin, sodium benzoate, yellow 6, red 40

This product is not manufactured or distributed by Johnson + Johnson Healthcare Products, distributor of Listerine

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Live Better

Antiseptic

Mouth

Rinse

CITRUS

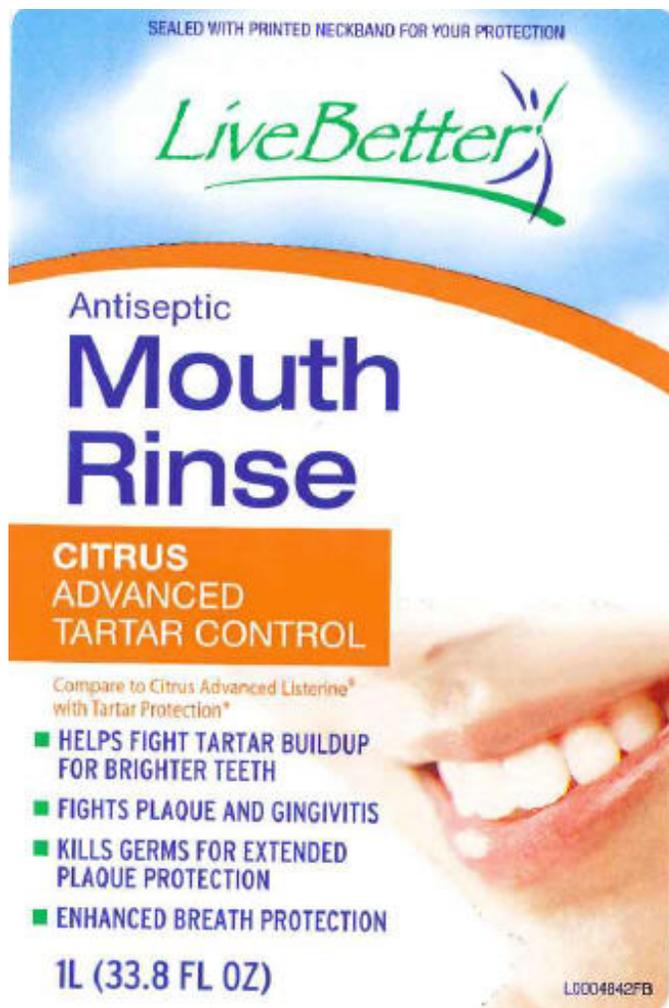
ADVANCED

TARTAR CONTROL

Compare to Citrus Advanced Listerine with Tartar Protection

•HELPS FIGHT TARTAR BUILDUP

- FOR BRIGHTER TEETH
- FIGHTS PLAQUE AND GINGIVITIS
 - KILLS GERMS FOR EXTENDED PLAQUE PROTECTION
 - ENHANCED BREATH PROTECTION
- 1L (33.8 FL OZ)



ANTISEPTIC

eucalyptol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51143-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	.092 mL in 100 L

MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	.042 mL in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	.060 mL in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	.064 mL in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51143-210-86	1 L in 1 BOTTLE, PLASTIC		
2	NDC:51143-210-12	1.5 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/19/2010	

Labeler - Onpoint, Inc (001367366)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture