ADVANCED ANTISEPTIC - eucalyptol mouthwash Demoulas Super Markets, 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 0.042% 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 guns, pus from the gumline, loose teeth or increased spacing between the teeth. See your dentist immediately. This may be signs of periodontitis a serious form of gum disease.

Stop use and as 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 year of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then pit out; do not swallow children under 12 year 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 (590 - 770 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

DISTRIBUTED BY DEMOULAS SUPER MARKETS, INC 875 EAST STREET TEWKSBURY, MASS. 01879 MADE IN THE USA

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

Sealed With Printed Neckband For Your Protection

Market Basket

Compare to Citrus Advanced Listerine with Tartar Protection

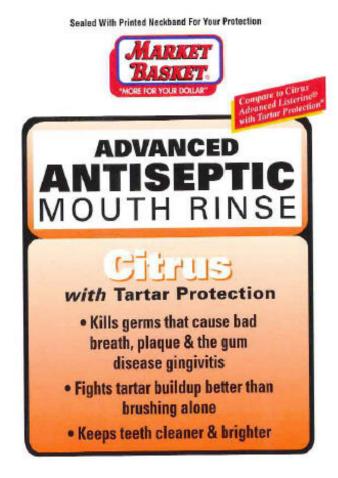
ADVANCED ANTISEPTIC MOUTH RINSE

Citrus

with Tartar Protection

- Kills germs that cause bad breath, plaque + the gum disease gingivitis
- Fights tartar buildup better than bushing alone
- Keeps teeth cleaner + brighter

1L (33.8 FL OZ)



Drug Facts Active ingredients Purpose Eucalyptol 0.092%, Menthol 0.042% Antigingivitis, Antiplaque Methyl salicylate 0.060%, Thymol 0.064% 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 pensists for more than 2 weeks Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get nedical help or contact a Poison Control Center right away. Directions adults and children 12 years vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow of age and older 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, alcehol (21.6%), sorbitol solution, flavoring, PEG-40 hydrogenated caster oil, poloxamer 407, benzolc acid, zinc chloride, sucratose and/or sodium saccharin, sodium benzoate, yelllow 6, rad 40 This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine®.

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875 EAST STREET TEWKSBURY, MASS. 01876 MADE IN USA



DSP-TN-15000 DSP-M0-34 SDS-TN-15012

L0001807BB

1 L (33.8 FL OZ)

L0001807FB

ADVANCED ANTISEPTIC

eucalyptol mouthwash

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:53942-210

Route of Administration ORAL

Active Ingredient/Active Moiety

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

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.042 kg in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	.060 kg in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	.064 kg in 100 L

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
ZINC CHLORIDE (UNII: 86Q357L16B)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942-210-86	1 L in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	07/22/2010	

Labeler - Demoulas Super Markets, Inc (007869647)

Registrant - Vi Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture

Revised: 9/2010 Demoulas Super Markets, Inc