TARTAR CONTROL PLUS- eucalyptol, menthol, methyl salicylate, thymol mouthwash Demoulas 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 ingredient

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help control plaque that leads to gingivitis

Warnings

for this product

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 6 years to under 12 years of age - supervise use

children under 6 yeard of age - do not use

• 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 $(59^{\circ}-86^{\circ}F)$

Inactive ingredients

water, alcohol 21.6%, sorbitol, poloxamer 407, benzoic acid, zinc chloride, sodium benzoate, sucralose, flavor, sodium saccharin, blue 1

Dis claimer

This product is not manufactured or distribted by Johnson & Johnson Healthcare Products, distributor of Listerine Ultraclean With Everfresh Technology - Artic Mint.

Adverse Reactions

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC.

875 EAST STREET

TWEKSBURY, MA 01876

Principal Display Panel

Sealed With Printed Neckband For Your Protection

MARKET

BASKET

MORE FOR YOUR DOLLAR

Compare to Listerine

Ultraclean with Evervesh

Technology Artic Mint

Tartar Control Plus

ANTISEPTIC

MOUTH RINSE

Iceberg Mint

Antigingivitis/Antiplaque

Long lasting clean feel

Fresh breath with mouth-cooling sensation

Control tartar that can discolor teeth

Kills germs that cause bad breath,

Plaque & the gum disease gingivitis

1 L (33.8 FL OZ)



TARTAR CONTROL PLUS

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-434
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
ZINC CHLORIDE (UNII: 86Q357L16B)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53942-434- 86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/2 1/2 0 16	

Labeler - Demoulas Markets, Inc (007869647)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(53942-434)	

Revised: 2/2016 Demoulas Markets, Inc