

TARTAR CONTROL PLUS- eucalyptol, menthol, methyl salicylate, thymol mouthwash
TopCo Associates, LLC

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.

Top Care 434.000 434AC

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

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 years 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°-86°F)

Inactive ingredients

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

Disclaimer

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

Adverse Reactions

Distributed by Topco Associates LLC

Elk Grove, IL 60007

1-888-423-0139

topcare@topco.com

DSP-TN-15000

DSP-MO-34

principal display panel

COMPARE TO LISTERINE ULTRACLEAN WITH EVERFRES TECHNOLOGY ARCTIC MINT

TopCare

everyday

Tartar Control Plus

Antiseptic Mouthwash

ANTIGINGIVITIS/ANTIPLAQUE

ICEBERG BLUE

- Control tartar that can discolor teeth
- Kills germs that cause bad breath, plaque & the gum disease gingivitis
- Long-lasting clean feel

16.9 FL OZ (1 PT 0.9 FL OZ) 500 mL

TARTAR CONTROL PLUS

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-434
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: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
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
1	NDC:36800-434-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2013	
2	NDC:36800-434-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/01/2013	

Labeler - TopCo Associates, LLC (006935977)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-434)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-434)

Revised: 6/2022

TopCo Associates, LLC