ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Vi-Jon, 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.

Blue Mint Antiseptic Mouthrinse 664.003/664AT rev2-AU

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 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 (59º-77ºF)

Inactive ingredients

water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no.3

ADA Council Statement

The ADA Council on scientific affairs Acceptanc of Swan Blue Mint Antiseptic mouth rinse is based on its finding that the product is effective in helping to prevent and reduce gingivitis and plque above the gumline, when used as directed

Sealed With Printed Neckband For Your Protection

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine.

DSP-TN-15000 DSP-MO-34 SDS-TN-15012

Vi-Jon One Swan Drive

Smyrna, TN 37167

principal display panel

NDC 0869-0664-12

Swan

ANTISEPTIC

MOUTH RINSE

ice mint

Kills Germs that

Cause Bad Breath

Plaque & the Gum

Disease Gingivitis

Compare to active ingredients of Listerine* Sealed with printed neckband for your protection ADA Accepted American Dental Association 1.5 Liters (50.7 FL OZ)

ANTISEPTIC

Mouth Rinse

enjuague bucal antiséptico

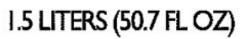
ice mint[®]

Kills Germs that Cause Bad Breath, Plaque & the Gum Disease Gingivitis.

menta de hielo

mata gérmenes que causan el mal aliento, la placa y gingivitis, la enfermedad de las encias

Compare to the active ingredients of Listerine**





NDC 0869-0664-12



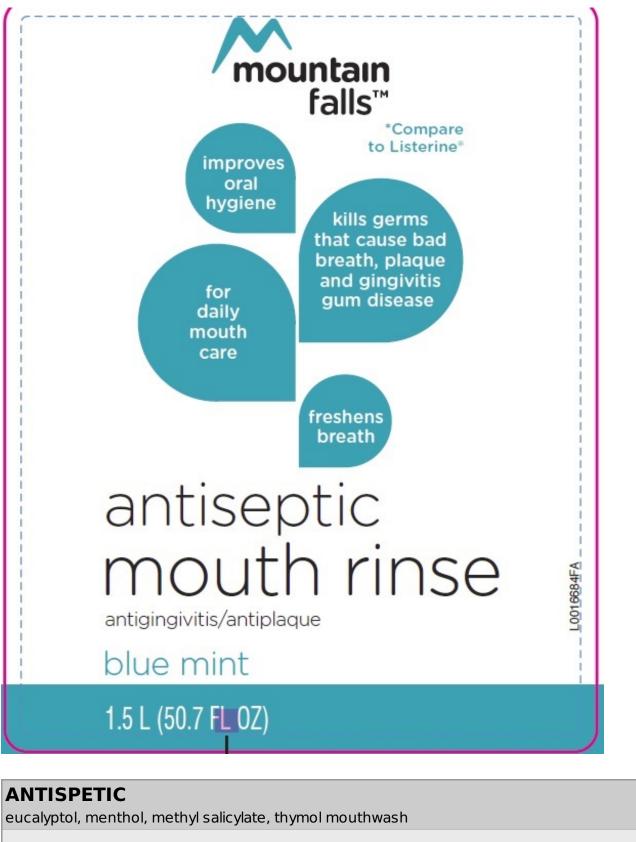
principal display panel

mountain

falls

Compare

to Listerine improves oral hygiene kills germs that cause bad breath, plaque and gingivitis gum disease for daily mouth care freshens breath antiseptic mouth rinse antiseptic mouth rinse antigingivitis/antiplaque blue mint 1.5 L (50.7 FL OZ)



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0664	
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:0414PZ4LPZ)	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: 85KN0B0MIM)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869- 0664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
2	NDC:0869- 0664-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
3	NDC:0869- 0664-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
4	NDC:0869- 0664-88	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
5	NDC:0869- 0664-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
6	NDC:0869- 0664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
7	NDC:0869- 0664-19	94 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1992	
-				

Marketing Information

OTC monograph not	
OTC monograph not final part356 07/15/1992	

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(0869-0664)	
Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(0869-0664)	

Revised: 3/2023

Vi-Jon, LLC