

**ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Jubilant, 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 rev 2 664AU**

Active ingredients

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 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, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, flavor, FD&C green no.3

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

Distributed by:

Jubilant LLC, Union, NJ 07083

www.PrinceSpring.Com

QUESTIONS? COMMENTS?

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DSP-TN-21091

DSP-MO-20087

principal display panel

PRINCE & SPRING

ANTISEPTIC MOUTHWASH

Blue Mint Flavored

Kills 99.9% of Germs Commonly Associated with Gingivitis

Fights Bad Breath

Helps Reduce Plaque

Contains 21.6% Alcohol

1.5 L (1 QT 1 PT 2.7 FL OZ) 50.7 FL OZ

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L0020756FA



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71569-664
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: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71569-664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2017	
2	NDC:71569-664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/03/2017	

Labeler - Jubilant, LLC (079508724)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(71569-664)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(71569-664)

