ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Shopko Store Operating Co, 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 66AU

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Claim

SHOPKO

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 (59°-77°F)

Inactive ingredients

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

Disclaimer

This product is not manufactured or distribted by Johnson & Johnson Healthcare Products, distributor of Cool Mint Listerine

Adverse Reactions

Manufactured by Vi-Jon, LLC., One Swan Dr., Smyrna, TN 37167 2012 Shopko Stores Operating Co., LLC www.shopko For consumer questions call 1-888-593-0593 SHOPKO Satisfaction Guaranteed BNy Refund Or Exchange DSP-TN-15000 DSP-MO-34 SDS-TN-15012

principal display panel

SHOPKO COMPARE TO THE INGREDIENTS OF LISTERINE Antiseptic Mouth Rinse Blue Mint Kills Germs that Cause Bad Beath, Plaque & The Gum Disease Gingivitis 1.5 Liters (50 .7 FL OZ)

Shopko

COMPANE TO THE ACTIVE INSPECIENTS OF LISTERINE -

Antiseptic Mouth Rinse

Blue Mint

Kills Germs That Cause Bad Breath, Plaque & The Gum Disease Gingivitis

1.5 Liters (50.7 FL OZ)

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-664	
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: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

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012- 664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2008	
2	NDC:37012- 664-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2008	
3	NDC:37012- 664-13	1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2008	
4	NDC:37012- 664-19	94 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2008	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	01/02/2008	

Labeler - Shopko Store Operating Co, LLC (023252638)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(37012-664)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(37012-664)	

Revised: 12/2022

Shopko Store Operating Co, LLC