# ANTISPETIC- eucalyptol, menthol, methyl salicylate and thymol mouthwash Vi-Jon

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.

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## **Drug Facts**

## **Active ingredients**

Active ingredients

Eucalyptol 0.0692%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

## **Purpose**

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Antigingivitis, antiplaque

#### Use

**Use** help control plaque that leads to gingivitis

## Warnings

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#### Do not use

**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

**Stop use and ask a dentist if** gingivitis, bleeding, or redness persists for more than 2 weeks.

## Keep out of reach of children.

**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**

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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 unmder 12 years of age - consult a dentist or doctor

• this rinse is not intended to replace brushing or flossing

## **Inactive ingredients**

**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 Safeway 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

## **Dis claimer**

This product is not manufactured or distribted by Johnson + Johnson Healthcare Products, distributor of Listerine

#### **Adverse Reactions**

Distributed by: Vi-Jon

One Swan Drive, Smyrna, TN 37167

## **Principal Display Panel**

Meets current TSA's guidelines for carry-on luggate

Swan

ANTISEPTIC

**MOUTH RINSE** 

ice mint

Kills Germs that

Cause Bad Breath

Plaque + the Gum

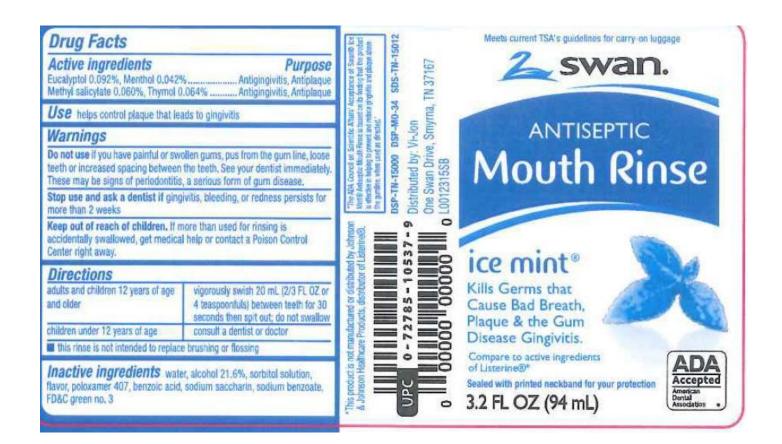
Disease Gingivitis

Compare to active ingredients

of Listerine

Sealed with printed neckband for your protection

3.2 FL OZ (94 mL)



#### **ANTISPETIC**

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0869-0664
Route of Administration	ORAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (EUCALYPTOL)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (MENTHOL)	MENTHOL	0.42 mg in 1 mL	
METHYL SALICYLATE (SALICYLIC ACID)	METHYL SALICYLATE	0.60 mg in 1 mL	
THYMOL (THYMOL)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER		
ALCOHOL		
SORBITOL		
POLOXAMER 407		
BENZOIC ACID		
SACCHARIN SO DIUM		
SO DIUM BENZO ATE		
FD&C GREEN NO. 3		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0869-0664-86	1000 mL in 1 BOTTLE, PLASTIC		
2 NDC:0869-0664-77	500 mL in 1 BOTTLE, PLASTIC		
3 NDC:0869-0664-69	250 mL in 1 BOTTLE, PLASTIC		
4 NDC:0869-0664-88	2000 mL in 1 BOTTLE, PLASTIC		
5 NDC:0869-0664-13	1250 mL in 1 BOTTLE, PLASTIC		
<b>6</b> NDC:0869-0664-12	1250 mL in 1 BOTTLE, PLASTIC		
7 NDC:0869-0664-19	94 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/15/1992	

## **Labeler -** Vi-Jon (790752542)

## **Registrant -** Vi-Jon (790752542)

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

Revised: 2/2013 Vi-Jon