

ANTISPETIC- eucalyptol, menthol, methyl salicylate and thymol mouthwash
Western Family Foods, Inc

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.

Drug Facts

Active ingredients

Active ingredients

Eucalyptol 0.0692%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Purpose

Antigingivitis, antiplaque

Use

Use help control plaque that leads to gingivitis

Warnings

Warnings

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

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

Other information cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F)

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 Acceptance 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 plaque above the gumline, when used as directed

Disclaimer

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

Adverse Reactions

Proudly dist. by Western Family Foods, Inc., P.O. Box 4057, Portland, OR 97208

www.westernfamily.com

Safety Sealed

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Principal display panel

WESTERN

FAMILY

ANTISEPTIC

Mouth Rinse

Kills Germs that

cause Bad Breath,

Plaque + the gum

disease Gingivitis

Blue Mint

ADA

Accepted

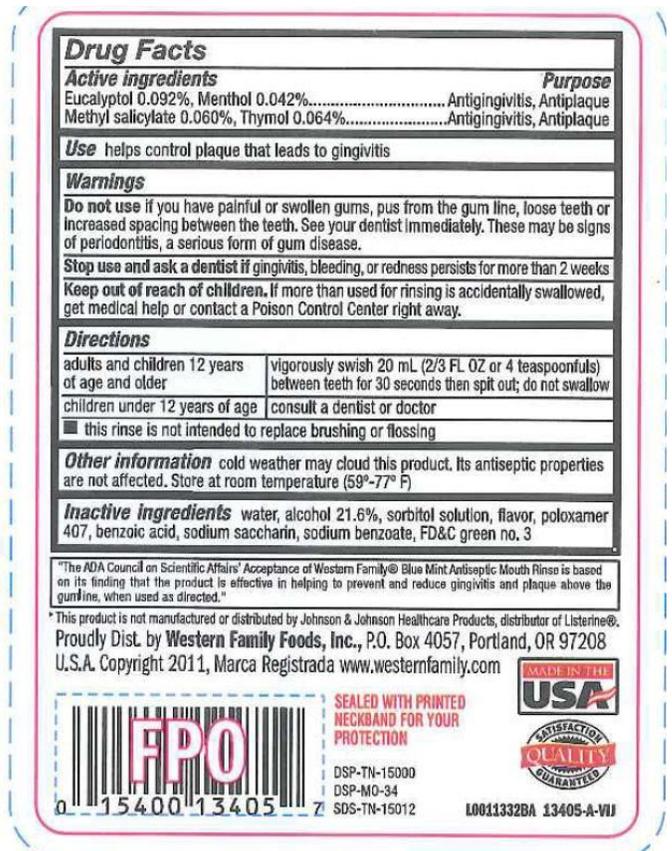
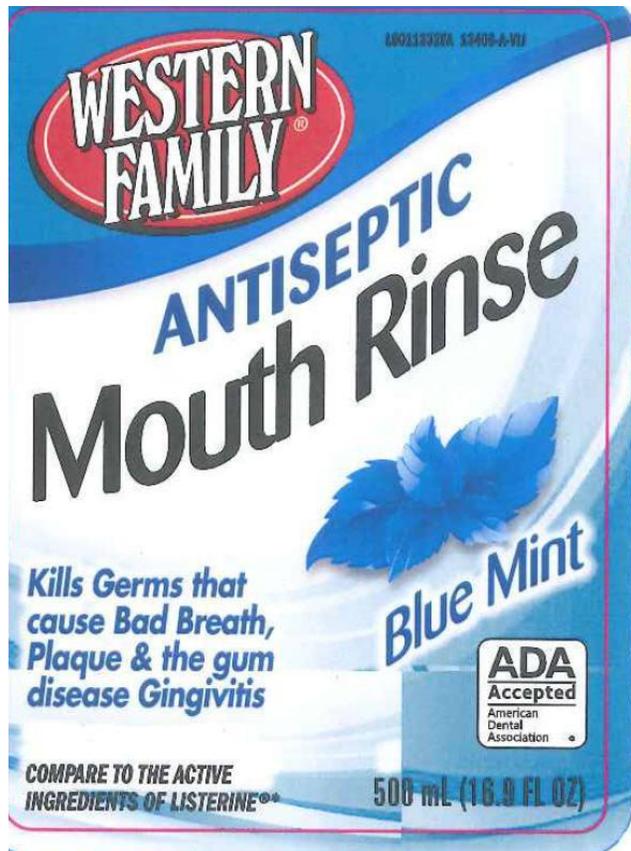
American

Dental

Association

COMPARE TO THE ACTIVE
INGREDIENTS OF LISTERINE

500 mL (16.9 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55312-664
Route of Administration	ORAL	DEA Schedule	

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 SODIUM	
SODIUM BENZOATE	
FD&C GREEN NO. 3	

--

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-664-86	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:55312-664-77	500 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	03/15/1998	

--

Labeler - Western Family Foods, Inc (192166072)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55312-664)