

ANTISPETIC- eucalyptol, menthol, methyl salicylate and thymol mouthwash
Safeway, 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

TEP

Sealed with printed neckband for your protection

Active ingredients

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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 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 Mouthwash 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

Adverse Reactions

DISTRIBUTED BY SAFEWAY INC.

P.O. BOX 99

PLEASANTON, CA 94566-0009

1-888-SAFEWAY/www.safeway.com

PRODUCT OF U.S.A.

Principal display panel

SAFEWAY

CARE

Quality Guaranteed

ANTISEPTIC

Mouthwash

antigingivitis/antiplaque

Blue Mint

Fights plaque & gingivitis

Kills germs that cause bad breath

ADA

Accepted

American

Dental

Association

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:21130-664
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:21130-664-86	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:21130-664-12	1500 mL in 1 BOTTLE, PLASTIC		
3	NDC:21130-664-77	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 - Safeway, Inc (009137209)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(21130-664)