AMBER MOUTH RINSE - eucalyptol, menthol, methyl salicylate, thymol liquid
Filo America

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 INGREDIENT

EUCALYPTOL 0.092%, MENTHOL 0.042%, METHYL SALICYLATE 0.060%, THYMOL 0.064%

PURPOSE

ANTIPLAQUE/ANTIGINGIVITIS

USES

TO HELP CONTROL PLAQUE THAT LEADS TO GINGIVITIS.

WARNINGS

DO NOT USE IF YOU HAVE PAINFUL OR SWOLLEN 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.

DO NOT USE FOR CHILDREN UNDER 12 YEARS OF AGE.

STOP USE AND ASK A DENTIST IF GINGIVITIS, BLEEDING OR REDNESS PERSISTS FOR MORE THAN 72 HOURS.

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 FLUID OUNCE OR 4 TEASPOONFULS) BETWEEN TEETH FOR 30 SECONDS THEN SPI9T 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.

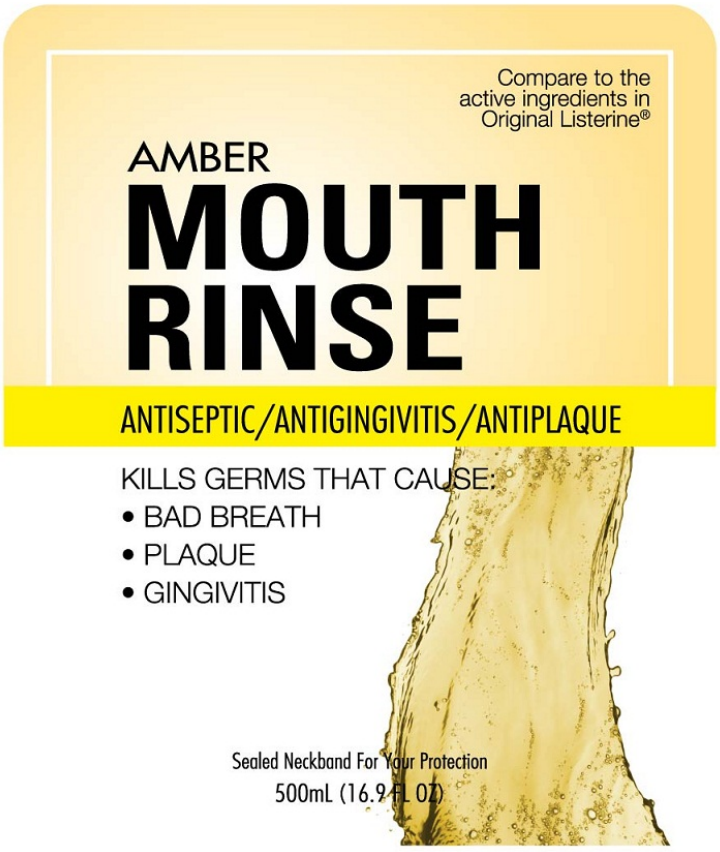
OTHER INFORMATION

COLD WATER MAY CLOUD THIS PRODUCT. ITS ANTISEPTIC PROPERTIES ARE NOT AFFECTED. STORE AT ROOM TEMPERATURE (59°-77°F).

INACTIVE INGREDIENTS:

WATER (AQUA), ALCOHOL (21.6%), SORBITOL SOLUTION, FLAVOR, POLOXAMER 407,

BENZOIC ACID, SODIUM SACCHARIN, SODIUM BENZOATE, YELLOW 5, BLUE 1



DRUG FACTS

Active Ingredient — **Purpose**
Eucalyptol, Menthol
Methyl Salicylate, Thymol ..... Antigingivitis, Antiplaque

Use Helps control plaque that leads to gingivitis.

Warnings

Do not use if you have painful or swollen 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. Do not give to children under 12 years of age.

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

Keep out of reach of children. Do not give to children under 12 years of age. 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 20mL (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 water may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°-77°F)

Inactive Ingredients Water, Alcohol (15%), Benzoic, Poloxamer 407, Sodium Benzoate, FD&C Yellow 5,FD&C Yellow 6,FD&C Blue 1

Made in China

7 93366 20034 3

This product is not manufactured or distributed by Pfizer Consumer Healthcare, a distributor of Listerine®.

DISTRIBUTED BY:
Filo America, P.O. Box 23592
Los Angeles, CA 90023
1-866-460-0322.

AMBER MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50438-303
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	0.6 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 YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-303-01	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	07/30/2013	

Labeler - Filo America (943873703)

Registrant - Ningbo Pulisi Daily Chemical Products Co., Ltd. (529047265)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-303)

Revised: 7/2013 Filo America