ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Wakefern Food Corp

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.

Mouthrinse 124

Active ingredients

Eucalyptol 0.092% Menthol 0.042% Methyl salicylate 0.060% Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help control plaque that leads to gingivitis

Warnings

For this product

Do not use

If you have painful or swollem 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 the rinse

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, sucralose and/or sodium saccharin, sodium benzoate, propylene glycol alginate, FD&C yellow no. 6, FD&C blue no. 1

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerne

Distributed By

Wakefern Food Corp.

5000 Riverside Drive

Keasbey, NJ 08832

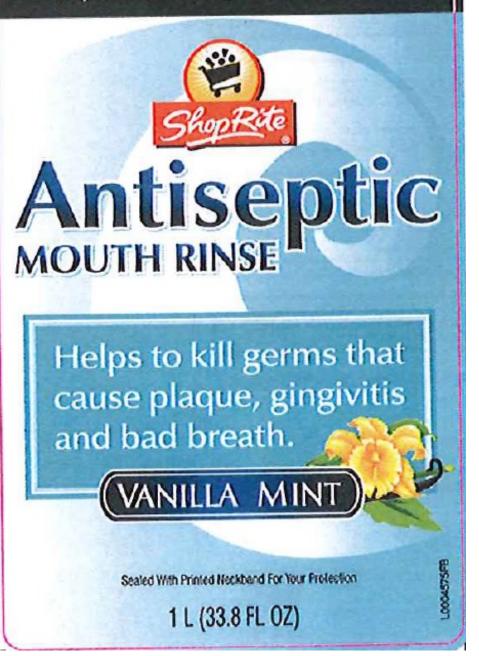
Call:1-800-shoprite

Contact Us: www.shoprite.com

principal display panel

Compare to the Active Ingredients of LISTERINE* SHOPRITE Antiseptic Mouth Rinse Helps to kill germs that cause plaque, gingivitis and bad breath VANILLA MINT Sealed With Printed Neckband For Your Protection 1L (33.8 FL OZ)





ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:	41190-124
Route of Administration	ORAL				
Active Ingredient/Active	Mojety				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
					0.02 ~~~

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)	
PROPYLENE GLYCOL ALGINATE (UNII: 26CD3J2R0C)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41190- 124-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2009		
Marketing Information					
	Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/04/2009	

Labeler - Wakefern Food Corp (069722418)

Registrant - Vi-Jon, LLC (790752542)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vi-Jon, LLC		790752542	manufacture(41190-124)		

Revised: 6/2022

Wakefern Food Corp