

ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash
American Sales Company

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.

Care One 318

TEP

Sealed With Printed Neckband For Your Protection

Active ingredients

Eucalyptol, Menthol, Methyl salicylate, Thymol

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 informatin

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

inactive ingredients

water, alcohol 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

ADA Statement

The ADA Council on Scientific Affairs Acceptance of Care One Antiseptic Mouth Rinse is based on it finding that the product is effective in helping to prevent and reduce gingivitis and plaque above the gumline, wuhen used as directed.

Disclaimer

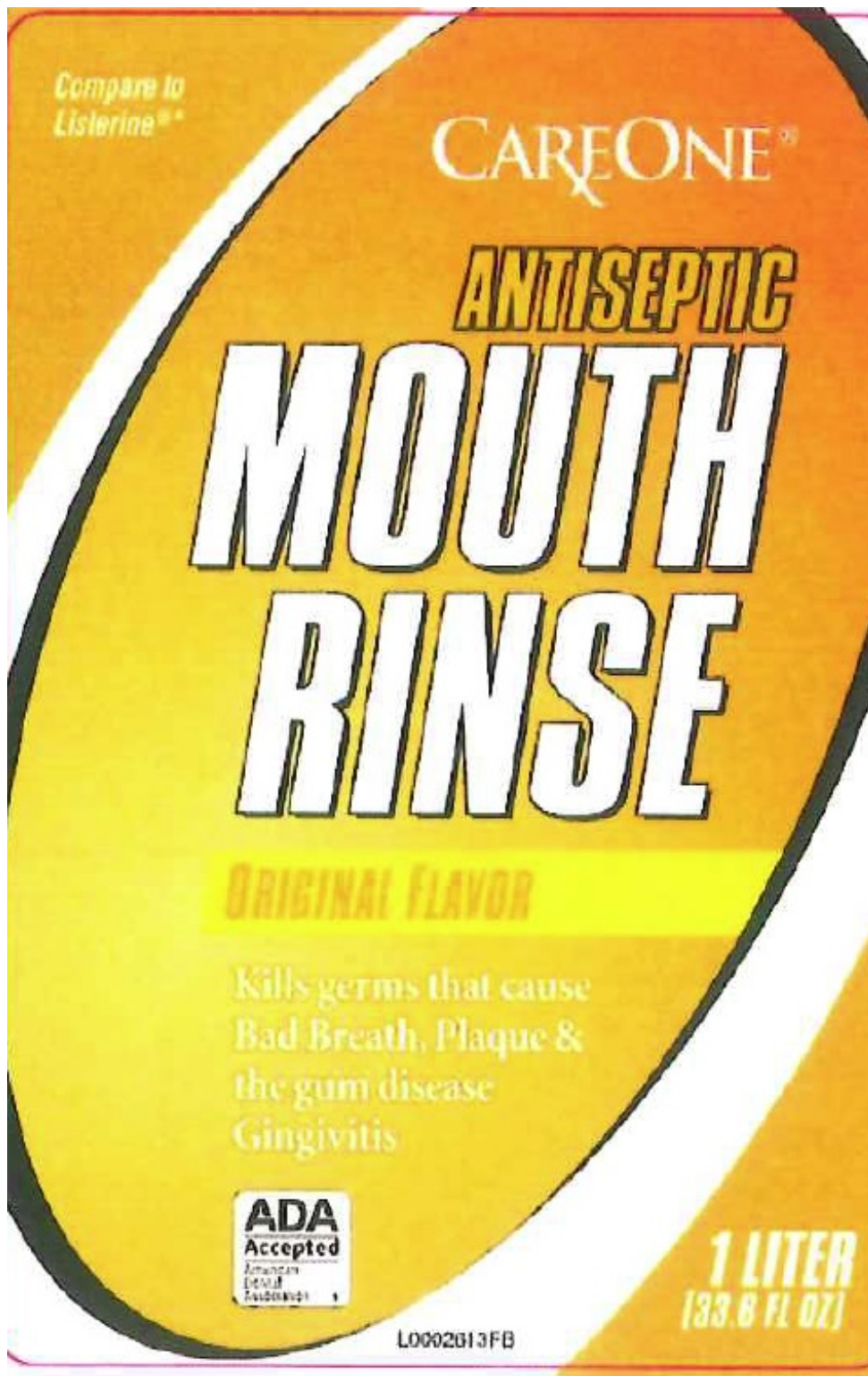
This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine.

Adverse Reaction

DISTRIBUTED BY
AMERICAN SALES COMPANY
4201 WALDEN AVENUE LANCASTER, NY 14086
318.003/318AH

princpal display panel

Compare to
Listerine
CARE ONE
ANTISEPTIC
MOUTH
RINSE
ORIGINAL FLAVOR
Kills germs that cause
Bad Breath, Plaque &
the gum disease Gingivitis
ADA
Accepted mm3.jpg
American
Dental
Association
1 LITER
(33.8 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-318
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: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	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)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-318-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/13/1989	
2	NDC:41520-318-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/13/1989	
3	NDC:41520-318-69	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/13/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/13/1989	

Labeler - American Sales Company (809183973)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(41520-318)