

ORIGINAL ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash

Duane Reade

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 ingredient

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

Purpose

Antiginivitis, 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 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 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

DISTRIBUTED BY DUANE READE

(866)375-6925

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duanereade.com

318.003/318AH

Principal Display Panel

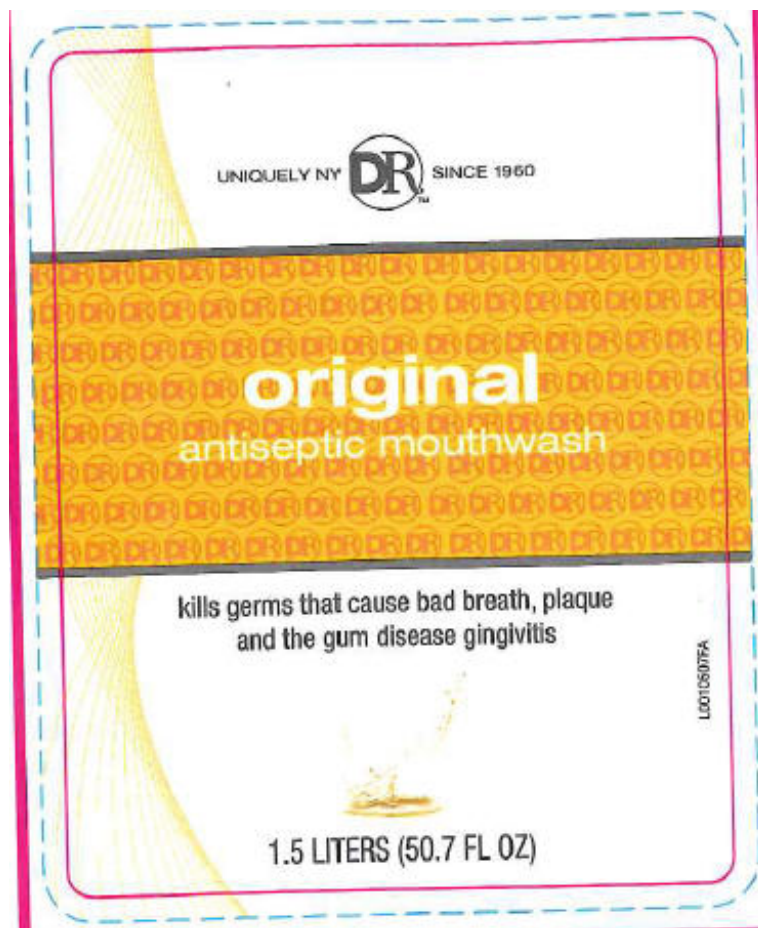
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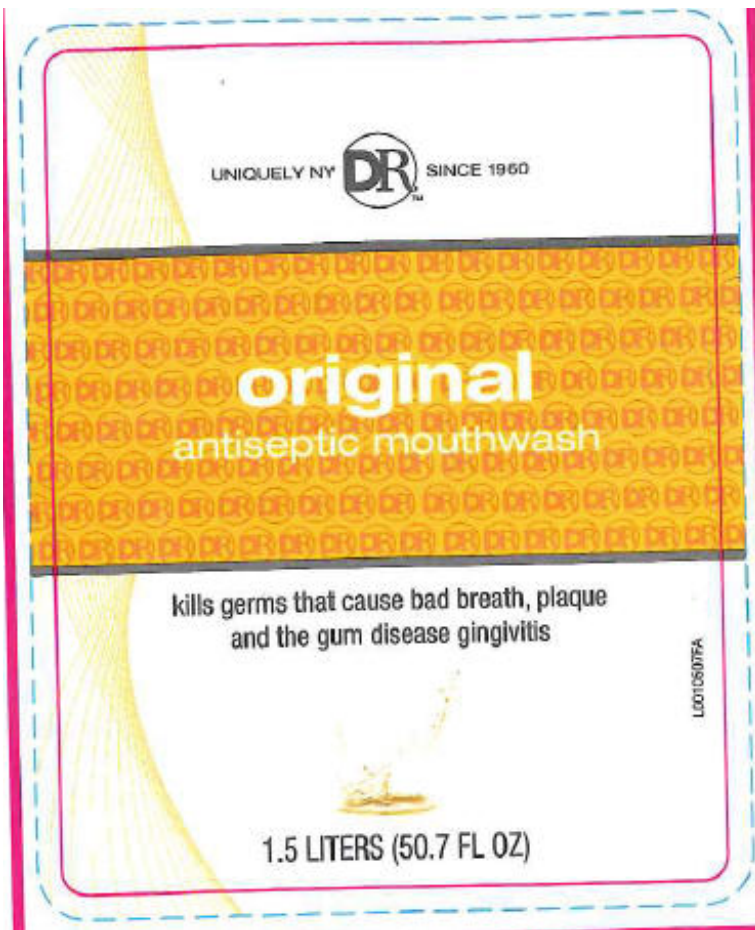
original

antiseptic mouthwash

kills germs that cause bad breath, plaque and the gum disease gingivitis

1.5 LITERS (50.7 FL OZ)





ORIGINAL ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67732-318
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	.092 kg in 100 L
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.042 kg in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	.060 kg in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	.064 kg in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

CARAMEL (UNII: T9D99G2B1R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67732-318-86	1 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/1992	
2	NDC:67732-318-12	1.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/1992	
3	NDC:67732-318-77	.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/1992	
4	NDC:67732-318-69	.25 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/1992	
5	NDC:67732-318-13	1.2 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/15/1992	

Labeler - Duane Reade (011988995)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(67732-318)

Revised: 3/2018

Duane Reade