

COLGATE PHOS-FLUR ORTHO DEFENSE ALCOHOL FREE ANTICAVITY GUSHING GRAPE FLUORIDE- sodium fluoride rinse

Team Technologies, 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.

Colgate® Phos-Flur® Ortho Defense® Alcohol Free Anticavity Gushing Grape Fluoride Rinse

Drug Facts

Active ingredient

Sodium fluoride 0.04% (0.02% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

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 6 years of age and older	<ul style="list-style-type: none">• use once a day after brushing your teeth with a toothpaste• vigorously swish 10 milliliters (10 mL mark on cap or 2 teaspoonfuls) of rinse between your teeth for 1 minute then spit out• do not swallow the rinse• do not eat or drink for 30 minutes after rinsing• instruct children under 12 years of age in good rinsing habits (to minimize swallowing)• supervise children as necessary until capable of using without supervision
children under 6 years of age	<ul style="list-style-type: none">• ask a dentist or physician

Inactive ingredients

water, sorbitol, sodium phosphate, flavor, potassium sorbate, phosphoric acid, polysorbate 20, FD&C blue no. 1, FD&C red no. 40

Other Information

store at controlled room temperature 68 – 77° F (20 – 25°C)

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

ALCOHOL FREE*

Colgate®

Phos•Flur®

Ortho Defense®

Anticavity Fluoride Rinse

IDEAL PROTECTION

WHILE WEARING BRACES

- 1. ORTHODONTIST RECOMMENDED**
- 2. HELPS STRENGTHEN ENAMEL**
- 3. HELPS PREVENT CAVITIES**

GUSHING GRAPE

16.9 FL OZ (1.05 PT) 500 mL

IMPORTANT: Read directions for proper use

ADA

Accepted

American

Dental

Association®

P9895933

Phos Flur Artwork



NOTICE: Do not use if printed band is broken or missing. To open, squeeze cap and turn. Reclose tightly.

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Questions? 1-800-468-6502	
*Does Not Contain Ethyl Alcohol P9895934	
 <p>"The ADA Council on Scientific Affairs' Acceptance of Colgate® Phos-Flur® Ortho Defense (Bubble Gum, Cool Mint, Gushing Grape) is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."</p>	
Dist. by: COLGATE-PALMOLIVE COMPANY New York, NY 10022 MADE IN U.S.A. www.colgate.com	

COLGATE PHOS-FLUR ORTHO DEFENSE ALCOHOL FREE ANTICAVITY GUSHING GRAPE FLUORIDE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67659-034(NDC:0126-0034)
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67659-034-30	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/01/2017	

Labeler - Team Technologies, Inc. (192339703)

Registrant - Team Technologies, Inc. (192339703)

Establishment

Name	Address	ID/FEI	Business Operations
Team Technologies, Inc		079337800	repack(67659-034) , relabel(67659-034)