

**COLGATE PHOS-FLUR ORTHO DEFENSE ALCOHOL FREE ANTICAVITY MINT
FLUORIDE- sodium fluoride rinse
Colgate Oral Pharmaceuticals, 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 Mint Fluoride

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, poloxamer 338, polysorbate 20, propylene glycol, flavor, potassium sorbate, phosphoric acid, FD&C blue no. 1

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®

Anticavity Fluoride Rinse

Ortho

Defense®

Phos • Flur®

Sodium Fluoride Acidulated

Phosphate Solution

IDEAL PROTECTION

WHILE WEARING BRACES

- ☐ ORTHODONTIST RECOMMENDED
- ☐ HELPS STRENGTHEN ENAMEL
- ☐ HELPS PREVENT CAVITIES

16.9 FL OZ

(1.05 PT)

500 mL

MINT

ADA

Accepted

American

Dental

Association®

IMPORTANT: Read

directions for proper use

P9933378

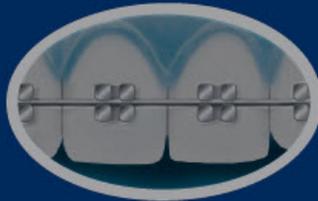
Protection between Brushings

ALCOHOL FREE

Colgate[®]
Anticavity Fluoride Rinse

Ortho Defense[®]

Phos · Flur. | Sodium Fluoride Acidulated Phosphate Solution



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WHILE WEARING BRACES**

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16.9 FL OZ
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500 mL



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Protection between Brushings

P9933378

CAP SEALED WITH PRINTED BAND

To Open: Remove printed band; squeeze cap and turn.

To Close: Turn cap until it clicks.

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***Does Not Contain Ethyl Alcohol**



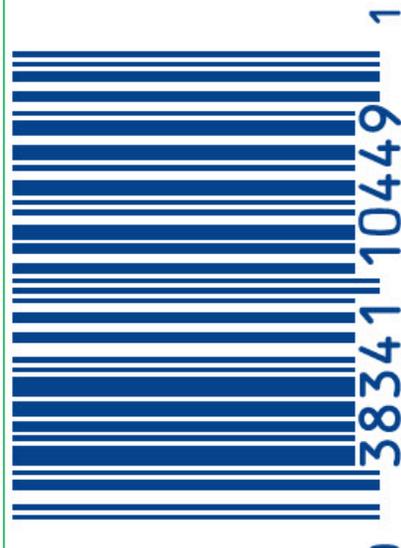
"The ADA Council on Scientific Affairs' Acceptance of Colgate® Phos-Flur® Ortho Defense® (Mint, Gushing Grape) is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."



Dist. by:
COLGATE-PALMOLIVE COMPANY
New York, NY 10022 U.S.A.

www.colgate.com

00010150



COLGATE PHOS-FLUR ORTHO DEFENSE ALCOHOL FREE ANTICAVITY MINT FLUORIDE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0126-0032
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)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0032-46	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	01/12/2011	

Labeler - Colgate Oral Pharmaceuticals, Inc. (968801118)

Registrant - Colgate-Palmolive Company (001344381)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive		785047999	MANUFACTURE(0126-0032)

Revised: 12/2019

Colgate Oral Pharmaceuticals, Inc.