COLGATE PHOS-FLUR ORTHO DEFENSE ALCOHOL FREE ANTICAVITY MINT FLUORIDE- sodium fluoride rinse Colgate Oral Pharmaceuticals, Inc.

 $\label{eq:colgate} \textbf{Colgate}^{\$} \ \textbf{Phos-Flur}_{\$} \ \textbf{Ortho Defense}^{\$} \ \textbf{Alcohol Free Anticavity Mint Fluoride} \\ \textbf{\textit{Drug Facts}}$

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	as not car or arrivers so minimized area.
children under 6 years of age	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



Ortho Defense®

Phos · Flur. | Sodium Fluoride Acidulated Phosphate Solution



IDEAL PROTECTION WHILE WEARING BRACES

- √ ORTHODONTIST RECOMMENDED
 - **✓ HELPS STRENGTHEN ENAMEL**
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16.9 FL OZ (1.05 PT) 500 mL





IMPORTANT: Read directions for proper use

Protection between Brushings

CAP SEALED WITH PRINTED BAND

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

To Close: Turn cap until it clicks.

Drug Facts

Active ingredient

Purpose

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

...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

- 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 · ask a dentist or physician

Other information store at controlled room temperature $68 - 77^{\circ}$ F ($20 - 25^{\circ}$ C)

Inactive ingredients water, sorbitol, sodium phosphate, poloxamer 338,

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

Questions? 1-800-468-6502

*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."

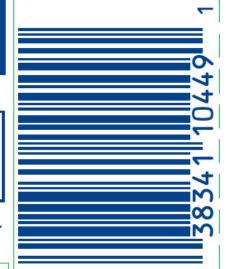


Dist. by:

COLGATE-PALMOLIVE COMPANY New York. NY 10022 U.S.A.

www.colgate.com

D0010150



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: 059QF0KO0R)

SORBITOL (UNII: 506T60A25R)

SODIUM PHOSPHATE (UNII: SE337SVY37)

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: H3R47K3TBD)

Product Characteristics

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 DRUG	M021	01/12/2011	

Labeler - Colgate Oral Pharmaceuticals, Inc. (968801118)

Revised: 1/2024 Colgate Oral Pharmaceuticals, Inc.