PHOS-FLUR- sodium fluoride gel, dentifrice
Colgate Oral Pharmaceuticals, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Phos•Flur®
Gel

1.1% Sodium Fluoride and
Acidulated Phosphate Gel

Rx ONLY

DESCRIPTION

Phos-Flur® Gel contains 0.5% fluoride ion (F-) from 1.1% sodium fluoride in an aqueous gel containing 0.1 molar phosphate, pH 5.1. For daily self-topical use as a dental caries preventative in adults and pediatric patients age 6 years and over. This prescription product is not a dentifrice.

Active Ingredient

Sodium Fluoride 1.1% (w/v).

Inactive Ingredients

butylparaben, disodium EDTA, ethylparaben, flavor, glycerin, methylparaben, PEG-12, phosphoric acid, poloxamer 407, polysorbate 20, propylene glycol, propyl paraben, sodium benzoate, sodium phosphate, sodium saccharin, water, xanthan gum, D&C yellow no. 10, FD&C blue no.1

CLINICAL PHARMACOLOGY

Frequent topical applications to the teeth with preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhance penetration of the fluoride ion into tooth enamel.

INDICATIONS AND USAGE

A dental caries preventive, for once daily self-applied topical use. It is well established that 1.1% sodium fluoride in an acidulated gel is safe and extraordinarily effective as a caries preventive in orthodontic patients when applied frequently with mouthpiece applicators.[1,2,3,4,5] Phos-Flur® Gel in a squeeze tube is a particularly convenient dosage form which permits the application of a thin ribbon of gel onto a toothbrush as well as a mouthpiece tray.

CONTRAINDICATIONS

Do not use in pediatric patients under age 6 years unless recommended by a dentist or physician.

WARNINGS

Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially in the areas with high fluoride concentration in drinking water. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of gel. Use cautiously in patients with porcelain or ceramic restorations as per PRECAUTIONS below. Read

directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS

General

Laboratory tests indicate that repeated use of acidulated phosphate fluoride topical gel may cause dulling of porcelain and ceramic restorations unless protected from contact. Do not place in porcelain or glass containers. Not for systemic treatment. DO NOT SWALLOW.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a study conducted in rodents, no carcinogenesis was found in male and female mice and female rats treated with fluoride at dose levels ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported in male rats treated with 2.5 and 4.1 mg/kg of body weight. In a second study, no carcinogenesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological data provide no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of human cancer.

Fluoride ion is not mutagenic in standard bacterial systems. It has been shown that fluoride ion has potential to induce chromosome aberrations in cultured human and rodent cells at doses much higher than those to which humans are exposed. *In vivo* data are conflicting. Some studies report chromosome damage in rodents, while other studies using similar protocols report negative results.

Potential adverse reproductive effects of fluoride exposure in humans has not been adequately evaluated. Adverse effects on reproduction were reported for rats, mice, fox, and cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Other studies conducted in rats demonstrated that lower concentrations of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities.

Pregnancy

Teratogenic Effects

Pregnancy Category B

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations.

There are no adequate and well-controlled studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during *in utero* development may result in skeletal fluorosis which becomes evident in childhood.

Nursing Mothers

It is not known if fluoride is excreted in human milk. However, many drugs are excreted in milk, and caution should be exercised when products containing fluoride are administered to a nursing woman. Reduced milk production was reported in farm-raised fox when the animals were fed a diet containing a high concentration of fluoride (98-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5 mg/kg of body weight.

Pediatric Use

The use of Phos-Flur® Gel in pediatric age groups 6 to 16 years as a caries preventive is supported by

pioneering clinical studies with 1.1% sodium fluoride gels in mouth trays in students age 11-14 years conducted by Englander, et al. [2,3,4] Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections.

Geriatric Use

Of the total number of subjects in clinical studies of 1.1% (w/v) sodium fluoride, 15 percent were 65 and over, while 1 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Contact with abraded or sensitive gingival tissue may produce discomfort. Allergic reactions and other idiosyncrasies have been rarely reported.

OVERDOSAGE

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg of body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.

A treatment dose (a thin ribbon) of Phos-Flur® Gel contains approximately 1.31 mg fluoride. One 1.8 oz. net wt. tube contains approximately 247 mg fluoride.

DOSAGE AND ADMINISTRATION

Follow these instructions unless otherwise instructed by your dental professional:

1. Adults and pediatric patients, ages 6-16 years, use once daily preferably at bedtime. After brushing with your normal toothpaste, rinse thoroughly. Apply a ribbon of Phos-Flur® Gel to the teeth with a toothbrush or mouthtray for at least one minute.
2. After use, adults expectorate gel. For best results, do not eat, drink or rinse for 30 minutes. Pediatric patients ages 6-16 years expectorate gel after use and rinse mouth thoroughly.

HOW SUPPLIED

1.8 oz. (56 g) net wt. plastic tubes.
Mint: NDC 0126-0131-66

STORAGE

Store at controlled room temperature, 68-77°F (20-25°C).

REFERENCES

1. American Dental Association, Council on Dental Therapeutics, Fluoride compounds, In: Accepted Dental Therapeutics, Ed. 40, Chicago, ADA, 405-407 (1984).
2. H.R. Englander et al., Clinical Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 75, 638-644 (1967).
3. H.R. Englander et al., Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 78, 783-787 (1969).
4. H.R. Englander et al., Incremental Rates of Dental Caries After Repeated Topical Sodium Fluoride Applications in Children With Lifelong Consumption of Fluoridated Water, JADA 82, 354-358, (1971).
5. Hirschfield RE et al: Angle Orthod., 44 (3): 218-221, 1994.

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PRINCIPAL DISPLAY PANEL - 51 g Tube Carton

Colgate®

Phos•Flur®
Gel

Rx ONLY

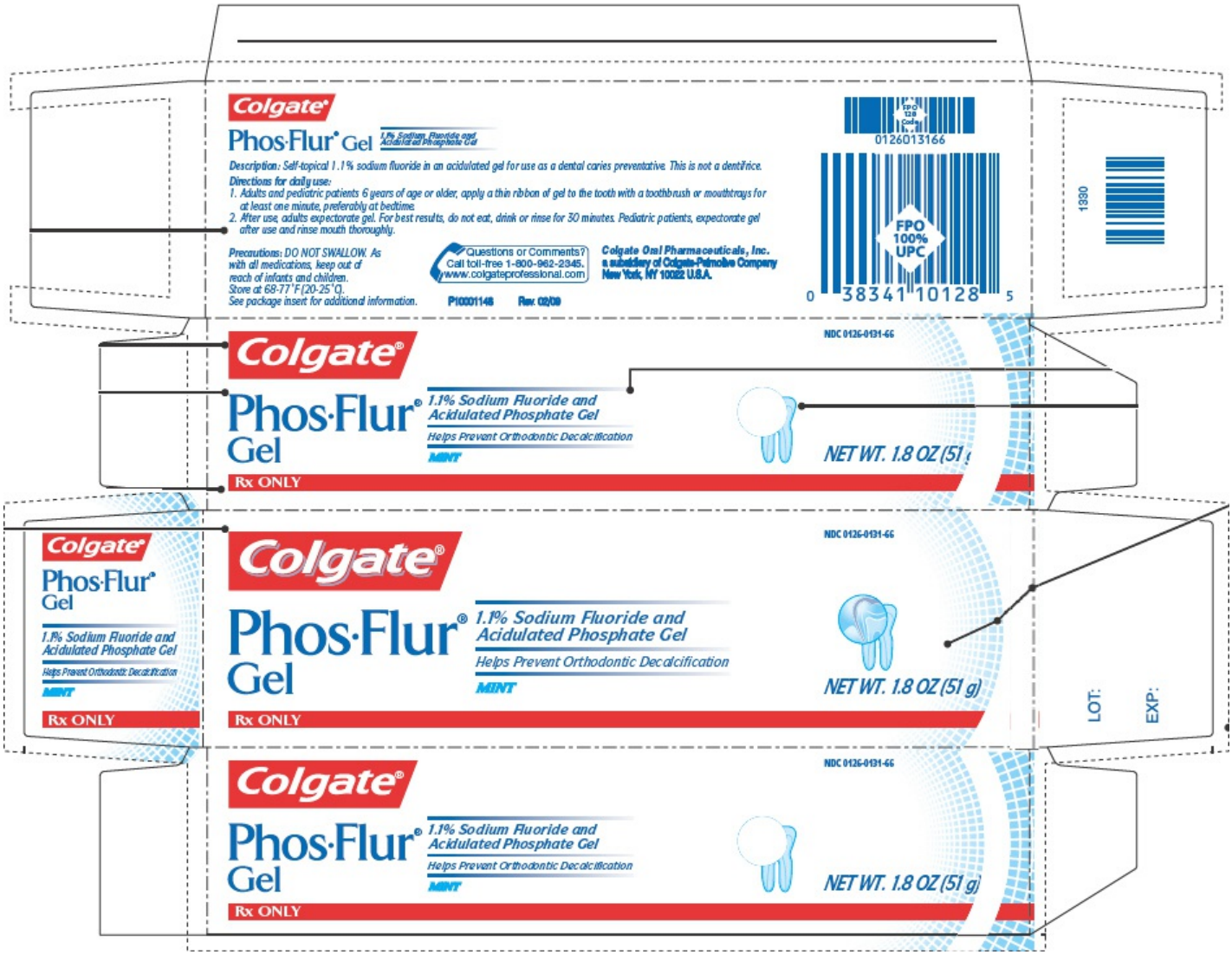
1.1% Sodium Fluoride and
Acidulated Phosphate Gel

Helps Prevent Orthodontic Decalcification

MINT

NDC 0126-0131-66

NET WT. 1.8 OZ (51 g)



PHOS-FLUR

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0126-0131
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	11 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	

Sodium Phosphate, Monobasic (UNII: 3980JIH2SW)	
Poloxamer 338 (UNII: F75JV2T505)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Polysorbate 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	GREEN (viscous, translucent)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0131-66	1 in 1 CARTON		
1		51 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/29/2012	

Labeler - Colgate Oral Pharmaceuticals, Inc. (055002195)

Revised: 9/2012 Colgate Oral Pharmaceuticals, Inc.