NEUTRAL SODIUM FLUORIDE 0.2% DENTAL RINSE- sodium fluoride rinse
Cypress Pharmaceutical, 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.

Neutral Sodium Fluoride 0.2% Dental Rinse

NDC 60258-158-16

Neutral Sodium Fluoride 0.2%

Dental Rinse

Mint Flavor

Rx Only

Cypress Pharmaceutical, Inc.

16 fl oz (1 pt) (473 mL)

Description: Neutral Sodium Fluoride 0.2% Dental Rinse is a mint-flavored, neutral, aqueous solution containing 6% alcohol.

ACTIVE INGREDIENT: Sodium Fluoride 0.2% (w/v). Contains: FD and C Blue #1.

INACTIVE INGREDIENT: Purified water, Glycerin, Alcohol 6% (v/v), Xylitol, Sodium Benzoate, Flavor, Magna Sweet, FD and C Blue #1.

CLINICAL PHARMACOLOGY: Topical application of sodium fluoride increases tooth resistance to acid dissolution, promotes remineralzation, and inhibits the cariogenic microbial process.

INDICATIONS AND USAGE: For once-weekly use as a dental caries preventative in pediatric patients.

WARNINGS: DO NOT SWALLOW. Keep out of reach of infants and children.

DOSAGE AND ADMINISTRATION: For caries- Adults and pediatric patients over 6 years, 2 teaspoonfuls (10mL) once a week, preferably at bedtime after thoroughly brushing teeth, rinse vigorously around and between teeth for one minute, then expectorate. DO NOT SWALLOW. For maximum benefit, do not eat, drink, or rinse mouth for at least 30 minutes after treatment.

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

See package insert for additional information.

CNRG06

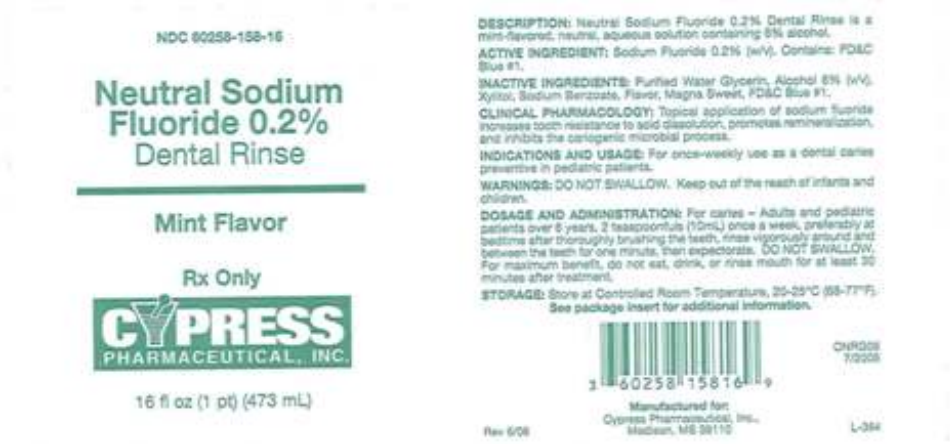
7/2008

Rev 6/06

Manufactured for:

Cypress Pharmaceutical, Inc.,

Madison, MS 39110



DESCRIPTION

Neutral Sodium Fluoride 0.2% Dental Rinse is a mint-flavored, neutral, aqueous solution containing 6% alcohol.

Active ingredient: Sodium Fluoride 0.2% (w/v). Contains: FD and C Blue #1.

Inactive ingredients: Purified water, Glycerin, Alcohol 6% (v/v), Xylitol, Sodium Benzoate, Flavor, Magna Sweet, FD and C Blue #1.

CLINICAL PHARMACOLOGY

Topical application of sodium fluoride increases tooth resistance to acid dissolution, promotes remineralzation, and inhibits the cariogenic microbial process.

INDICATIONS AND USAGE

A dental caries preventative for weekly self-applied topical use. Weekly rinsing with a neutral 0.2% sodium fluoride solution protects against dental caries in pediatric patients. Neutral Sodium Fluoride 0.2% Dental Rinse provides a ready- to-use preparation for convenient administration and favorable compliance. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)

CONTRAINDICATIONS

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

WARNINGS

Keep out of reach of infants and children. Pediatric patients under age 12 should be supervised in the use of this product. Patients under age 6 require special supervision to prevent repeated swallowing of rinse since they frequently swallow significant amounts while rinsing. Prolonged daily ingestion may result in dental fluorosis in patients under age 6, especially if water fluoridation exceeds 0.6 ppm. Read directions carefully before using.

PRECAUTIONS

General: Not for systemic treatment. DO NOT SWALLOW.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

No carcinogenesis was found in mice or female rats treated with fluoride at doses ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported in rats treated with 2.5 and 4.1 mg/kg of body weight. In another study, no carcinogenesis was observed in rats 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 but has been associated with chromosome aberrations in cultured human and rodent cells at doses much higher than expected human exposures. Some in vivo 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 litter size or fetal weight and did not increase 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 Neutral Sodium Fluoride 0.2% Dental Rinse as a weekly caries preventative in pediatric patients aged 6 to 16 years is supported by adequate and well-controlled clinical studies in students aged 6 to 12 years.1-3 Safety and effectiveness in pediatric patients below the ages 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

In patients with mucositis, gingival tissues may be hypersensitive to flavor or alcohol present in formulation. Allergic reactions and other idiosyncrasies are 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)has 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) has 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 (10 mL or two teaspoonfuls) of Neutral Sodium Fluoride 0.2% Dental Rinse contains approximately 9 mg of fluoride one 16 fl oz bottle contains approximately 429 mg fluoride.

DOSAGE AND ADMINISTRATION

For caries- Adults and pediatric patients over age 6 years, 2 teaspoonfuls (10mL) once a week, preferably at bedtime after thoroughly brushing teeth, rinse vigorously around and between teeth for one minute, then expectorate. DO NOT SWALLOW. For maximum benefit, do not eat, drink, or rinse mouth for at least 30 minutes afterwards.

HOW SUPPLIED

Plastic bottle with child-resistant closure containing 16 fl oz (473 mL) (NDC 60258-158-16).

STORAGE

Store at Controlled Room Temperature, 20-25°C (68-77°F).

REFERENCES

1. American Dental Association, Accepted Dental Therapeutics, Ed. 40, Chicago(1984): 403. 2. Ibid., p. 405-407. 3. L.W. Ripa, G.S. Leske, and A. Sposato, "Supervised Weekly Rinsing with a 0.2% Neutral NaF Solution: Final Results of a Demonstration Program after Six School Years" J. Pub. Health Dent, 43 (1983): 53-62. 4. Driscoll WS, et al. "Caries- preventative effects on school children daily and weekly fluoride mouthrinsing in a fluoridated community: final results after 30 months" JADA. 1982;105:1010-1013.

Cypress Pharmaceutical, Inc.

6/06

I327

Manufactured for:

Cypress Pharmaceutical, Inc.,

Madison, MS 39110

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CYPRESS PHARMACEUTICAL, INC.

Manufactured for:
Cypress Pharmaceutical, Inc.,
Madison, MS 39110

6/06 I327

CYPRESS PHARMACEUTICAL, INC.

Neutral Sodium Fluoride 0.2% Dental Rinse

DESCRIPTION: Neutral Sodium Fluoride 0.2% Dental Rinse brand of 0.2% neutral sodium fluoride is a mint-flavored, neutral, aqueous solution containing 6% alcohol.

Active Ingredients: Sodium Fluoride 0.2% (w/v).

Inactive Ingredients: Purified Water Glycerin, Alcohol 6% (v/v), Xylitol, Sodium Benzoate, Flavor, Magna Sweet, FD&C Blue #1.

CLINICAL PHARMACOLOGY: Topical application of sodium fluoride increases tooth resistance to acid dissolution, promotes remineralization, and inhibits the cariogenic microbial process.

INDICATIONS AND USAGE: A dental caries preventive for weekly self-applied topical use. Weekly rinsing with a neutral 0.2% sodium fluoride solution protects against dental caries in pediatric patients. Neutral Sodium Fluoride 0.2% Dental Rinse provides a ready-to-use preparation for convenient administration and favorable compliance. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)

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

WARNINGS: Keep out of the reach of infants and children. Pediatric patients under age 12 should be supervised in use of this product. Patients under age 6 require special supervision to prevent repeated swallowing of rinse since they frequently swallow significant amounts while rinsing. Prolonged daily ingestion may result in dental fluorosis in patients under age 6, especially if water fluoridation exceeds 0.6 ppm. Read directions carefully before using.

PRECAUTIONS :

General: Not for systemic treatment. DO NOT SWALLOW.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No carcinogenesis was found in mice or female rats treated with fluoride at doses 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 another study, no carcinogenesis was observed in rats 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.

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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 litter size or fetal weight and did not increase 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 (96-137 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 Neutral Sodium Fluoride 0.2% Dental Rinse as a weekly caries preventive in pediatric patients aged 6 to 16 years is supported by adequate and well-controlled clinical studies in students aged 6 to 12 years.[1-4] Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections.

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NEUTRAL SODIUM FLUORIDE 0.2% DENTAL RINSE

sodium fluoride rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:60258-158
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	9 mg in 10 mL

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60258-158-16	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved other		08/01/2006	

Labeler - Cypress Pharmaceutical, Inc. (790248942)

Registrant - Cypress Pharmaceutical, Inc. (790248942)

Establishment

Name	Address	ID/FEI	Business Operations
Emerald 3 Enterprises, Inc.		000000000	manufacture

Revised: 11/2009 Cypress Pharmaceutical, Inc.