FLUORIDEX- sodium fluoride paste, dentifrice
DENT-MAT HOLDINGS, LLC.

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.

Den-Mat Sensitive Toothpaste

HIGHLIGHTS OF PRESCRIBING INFORMATION

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These highlights do not include all the information needed to use Fluoridex toothpaste safely and effectively. See full prescribing information.

Fluoridex 1.1% Sodium Fluoride toothpaste for oral use

INDICATIONS AND USAGE

Fluoridex toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries. (1)

DOSAGE AND ADMINISTRATION

• Apply a thin ribbon or pea-sized amount of Fluoridex toothpaste to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute. (2)

• After use, adults should expectorate. For best results, do not eat, drink, or rinse for 30 minutes. Children, age 6-16, should expectorate after use and rinse mouth thoroughly. (2)

• Use twice daily as your normal dentifrice or as directed by your dental professional. (2)

DOSAGE FORMS AND STRENGTHS

• Daily Defense Mint: Green toothpaste containing 1.1% Sodium Fluoride (Mint). (3)

• Daily Defense Fruit: Pink toothpaste containing 1.1% Sodium Fluoride (Fruit). (3)

• Enhanced Whitening Mint: Green toothpaste containing 1.1% Sodium Fluoride (Mint). (3)

CONTRAINDICATIONS

Do not use in children under 6 years of age unless recommended by a dentist or physician. (4)

WARNINGS AND PRECAUTIONS

● DO NOT SWALLOW. (5)

● Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. (5)

● Repeated ingestion of high levels of fluoride may cause dental fluorosis. (5)

● Do not use this product longer than 4 weeks unless recommended by a dentist or physician. (5)

ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have rarely been reported. (6)

To report SUSPECTED ADVERSE REACTIONS, contact DenMat, at 1-800-752-2564, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

1 INDICATIONS AND USAGE

Fluoridex toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

2 DOSAGE AND ADMINISTRATION

• Follow these instructions or use as instructed by a dental professional.• Adults and children age 6 or older, apply a thin ribbon or pea-sized amount of Fluoridex toothpaste to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute.

After use:

• Adults should expectorate. For best results, do not eat, drink, or rinse for 30 minutes.

• Children, age 6 to 16, should expectorate after use and rinse mouth thoroughly.

• Use twice daily as your normal dentifrice or as directed by your dental professional.

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4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

DO NOT SWALLOW.

• Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

• Prolonged daily ingestion may result in various degrees of dental fluorosis in children with developing dentition, especially if the water fluoridation exceeds 0.6 ppm, since

younger children frequently cannot perform the brushing process without significant swallowing.

• Use in children under age 6 years requires special supervision to prevent repeated swallowing of toothpaste which could cause dental fluorosis.

• Read directions carefully before using.

• Keep out of reach of infants and children.

• Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

• See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

6 ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have rarely been reported.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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 tissues. 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 or well controlled clinical 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.

8.3 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.

8.4 Pediatric Use

The use of Fluoridex toothpaste in children age 6-16 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.2-4 Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water, and other sources) when prescribing the product for use in children. Please refer to the CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS sections.

8.5 Geriatric Use

Subjects referenced in clinical studies of 1.1% (w/v) sodium fluoride, included 15 percent age 65 and over, with 1 percent age 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger clients, 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 clients with impaired renal function. Because elderly clients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 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.

11 DESCRIPTION

Fluoridex toothpaste is a self-applied topical fluoride dentifrice containing 1.1% (w/w) sodium fluoride for the prevention and control of dental caries. Daily Defense Mint: Each gram contains 5 mg of fluoride ion in a neutral pH base, consisting of Cellulose Gum, D&C Yellow No. 10, FD&C Blue No. 1, Flavor, Glycerin, Mica (and) Titanium Dioxide, Poloxamer 234, Silica, Sodium Laurel Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

Daily Defense Fruit: Each gram contains 5 mg of fluoride ion in a neutral pH base, consisting of Cellulose Gum, D&C Red No. 33, Flavor, Glycerin, Mica (and) Titanium Dioxide, Poloxamer 234, Silica, Sodium Laurel Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

Enhanced Whitening Mint: Each gram contains 5 mg of fluoride ion in a neutral pH base, consisting of Cellulose Gum, D&C Yellow No. 10, FD&C Blue No. 1, Flavor, Glycerin, Mica (and) Titanium Dioxide, Poloxamer 234, Silica, Sodium Laurel Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

12 CLINICAL PHARMACOLOGY

A treatment dose (a thin ribbon) of Fluoridex 5000 ppm sodium fluoride toothpaste contains 2.5 mg fluoride. A 4 oz. tube contains 566 mg fluoride.

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.

13 NONCLINICAL TOXICOLOGY

13.1 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 cParcinogenesis 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 have 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 w eight) did not result in impaired fertility and reproductive capabilities.

15 REFERENCES

1. American Dental Association, Council on Dental Therapeutics, Fluoride compounds, In: Accepted Dental Therapeutics, Ed. 40, Chicago, ADA, 405-407, (1984).

2. Englander HR, et al., Clinical Anticaries Effect of Repeated Topical Sodium Fluroide Applications by Mouthpieces, JADA, 75, 638-644, (1967).

3. Englander HR, et al., Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 78, 783-787 (1969).

4. Englander HR, et al: JADA, 83:354-358, 1971.

16 HOW SUPPLIED/STORAGE AND HANDLING

4 oz. (112 g) net wt. tube

- Daily Defense Mint NDC 59883-016-04
- Daily Defense Fruit NDC 59883-015-04
- Enhanced Whitening Mint NDC 59883-020-04

Store at controlled room temperature 15°-30° C (59°-86° F)

Principal Display Panel

NDC59883-031-04

FLUORIDEX

SENSITIVITY

RELIEF

Prescription-Strength

Anticavity Toothpaste

CLEAN MINT

1.1% Sodium Fluoride 5000 PPM

5% Potassium Nitrate

Net Wt. 4 oz. (112 g) Rx Only

NDC 59883-031-04

FLUORIDEX®

SENSITIVITY RELIEF

Prescription-Strength Anticavity Toothpaste

CLEAN MINT

1.1% Sodium Fluoride 5000 PPM
5% Potassium Nitrate

Net Wt. 4 oz. (112 g) Rx Only

INDICATIONS AND USAGE:
Prescription fluoride toothpaste for use as part of a professional program for the prevention and control of dental caries.

ACTIVE INGREDIENTS:
1.1% Sodium Fluoride,
5% Potassium Nitrate

INACTIVE INGREDIENTS:
Cellulose Gum, D&C Yellow No. 10, FD&C Blue No. 1, Flavor, Glycerin, Mica (and) Titanium Dioxide, Poloxamer 234, Silica, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

DIRECTIONS FOR USE:
This prescription toothpaste is recommended for adults and children 12 years of age and older. Children under 12 years of age: Consult a dentist or doctor. Use twice daily as your normal dentifrice or as directed by your dental professional.

1. Apply a thin ribbon or pea-sized amount of Fluoridex Sensitivity Relief Toothpaste to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute.

2. After Use: Adults expectorate. For best results, do not eat, drink or rinse for 30 minutes. Children age 12-16, expectorate after use and rinse mouth thoroughly.

NOTE: Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

WARNINGS AND PRECAUTIONS:
DO NOT SWALLOW. Keep out of reach of children under 12 years of age. Read all instructions and prescribing information before using this product.

See package insert for additional information.

Store at controlled room temperature
15°-30°C (59°-86°F)

080262000 10/16SN

NDC 59883-031-04

FLUORIDEX®

SENSITIVITY RELIEF

Prescription-Strength Anticavity Toothpaste

CLEAN MINT

1.1% Sodium Fluoride 5000 PPM
5% Potassium Nitrate

Net Wt. 4 oz. (112 g) Rx Only

Manufactured for
Den-Mat Holdings, LLC
1017 W. Central Ave.
Lompoc, CA 93436

Questions or comments?
Call 1-800-752-2564

2262US

FLUORIDEX

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59883-031
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5 mg in 1 g

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT (Clean Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-031-04	1 in 1 BOX	12/21/2016	
1		112 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59883-031-05	24 g in 1 TUBE; Type 0: Not a Combination Product	08/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/21/2016	

Labeler - DENT-MAT HOLDINGS, LLC. (809857704)

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