# PRESCRIBING INFORMATION

Dayli® 1.1% Neutral Sodium Fluoride Gel

Rx only

**DESCRIPTION:** A topical fluoride brush-on dental gel containing 1.1% (w/w) sodium fluoride and 5% potassium nitrate for use a as prevention of hypersensitivity and dental caries.

**ACTIVE INGREDIENTS:**
Sodium fluoride 1.1% (w/w), potassium nitrate 5% (w/w)

**OTHER INGREDIENTS:**
Purified water, Xylitol, Hydroxyethyl Cellulose, Sucralose and Flavor.

**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:**
Dayli® 1.1% Neutral Sodium Fluoride Gel aids in the prevention of dental caries and hypersensitivity in adult and pediatric patients. Dayli® is a dental caries preventive for daily self-applied topical use and helps reduce the painful sensitivity of the teeth to cold, heat, acids, sweets or contact in adult patients and children 6 years of age and older. It is well established that 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators.1-4 Dayli®, a 1.1% sodium fluoride toothpaste with 5% potassium nitrate in 2 oz. laminate tube is easily applied onto a toothbrush. This prescription brush-on dental gel should be used once daily at bedtime in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis (See WARNINGS for exception).

**CONTRAINDICATIONS:**
Hypersensitivity to fluoride. Do not use in pediatric patients under age 6 years unless recommended by a dentist or physician.

**WARNINGS:**
READ DIRECTIONS CAREFULLY BEFORE USING. KEEP OUT OF REACH OF INFANTS AND CHILDREN.
Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under the age of 6 years, especially if the water fluoridation exceeds 0.6ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use by pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of gel which could cause dental fluorosis. 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.

**PRECAUTIONS:**
**General:** 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:** Safety and effectiveness in pediatric patients below the age of 12 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/w) 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:**
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 Dayli® 1.1% Neutral Sodium Fluoride Gel contains approximately 2.5 mg fluoride. A 2 oz. (57g) tube contains approximately 283 mg fluoride.

**DOSAGE AND ADMINISTRATION:**
Follow these instructions unless otherwise instructed by your dental professional:

- Adults and pediatric patients age 6 or older, apply a small amount of Dayli® 1.1% Neutral Sodium Fluoride Gel to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute.
- After use, adults expectorate, Pediatric patients, age 6-17, expectorate after use and rinse mouth thoroughly.
- Use once daily at bedtime in place of your regular toothpaste unless otherwise instructed by your dental professional.

**HOW SUPPLIED:**
2 oz. (57g) net wt. of gel in laminate tubes.
**Mint Flavor:** 2 oz tube - NDC 43679-613-02
**Grape Flavor:** 2 oz tube - NDC 43679-623-02

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

**CAUTION:**
Federal (USA) law prohibits dispensing without prescription.

**REFERENCES:** 1. Accepted Dental Therapeutics, Ed. 40, ADA, Chicago. P. 405-407, 1984. 2. Englander HR, Keyes et al: JADA 75:638-644, 1967. 3. Englander HR, et al: JADA78:783-787, 1969. 4. Englander HR, et al: JADA 83:354- 358, 1971.

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4330-C Matthews Indian Trail Road • Indian Trail, NC 28079
800.474.8681 • 704.849.2416 • fax: 704.849.2417 • preventech.com

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