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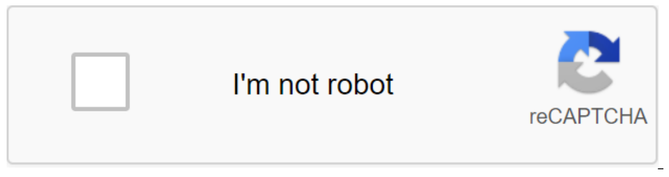

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Common name: Sodium fluoride and potassium nitrate (SOW dee um FLOR ide/po TAS ee um NYE trate) Brand: PreviDent 5000 Sensitive Medically, reviewed by Drugs.com. Last updated on September 9, 2020. Use PreviDent 5000 Sensitive: This supplement is used to prevent cavities. It is used to help sensitive teeth. What do I need to tell my doctor before taking PreviDent 5000 Sensitive? If you are allergic to PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate); any part of PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate); or any other medicine, food or substance. Tell your doctor about allergies and what signs you have had. If you have any of these health problems: bone problems, joint problems, kidney problems, or ulcers. If the fluoride in drinking water is more or equal to 0.6 parts per million. This is not a list of all medications or health problems that interact with PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate). Tell your doctor and pharmacist about all your medications (prescription or over-the-counter, natural foods, vitamins) and health problems. You should check to make sure it is safe for you to take PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate) with all your medications and health problems. Do not start, stop or change the dose of any drug without checking with a doctor. What things do I need to know or do while I take the PreviDent 5000 Sensitive? Tell all your health care providers that you are taking PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate). This includes your doctors, nurses, pharmacists and dentists. Tell your dentist if your teeth are stained or noticed. Take care of your teeth. You can often see the dentist. This medicine can cause harm if a large amount is swallowed. If a large amount of PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate) is swallowed, call your doctor or the toxicologist immediately. Different brands PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate) can have different doses for children. Talk to your doctor before giving PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate) to the baby. Tell your doctor if you are pregnant, plan to get pregnant, or breastfeed. You will need to talk about the benefits and risks for you and the child. What is the best way to take this medicine (PreviDent 5000 Sensitive)? Use PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate) on the doctor's order. Read all the information you've been given. Follow all the instructions carefully. Use instead of regular toothpaste if your doctor does not say otherwise. Brush like you're told and then spit it out. Do not swallow PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate). Rinse well and spit out water. What to do if I Dose? Use the missed dose as soon as you think about it. If it's close time for the next dose, skip the missed dose and return to normal time. Do not use 2 doses at the same time or additional doses. What are some side effects that I need to call my doctor about right away? WARNING: Even if it may be rare, some people may have very bad and sometimes fatal side effects when taking the drug. Tell your doctor or get medical attention right away if you have any of the following signs or symptoms that may be associated with a very bad side effect: Signs of an allergic reaction like a rash; Hives; Itching; red, swollen, blisters, or peeling skin with or without fever; wheezing; tightness in the chest or throat; problems with breathing, swallowing or talking; Unusual hoarseness; or swelling of the mouth, face, lips, tongue or throat. Very upset stomach or vomited. What are some of the other side effects of the PreviDent 5000 Sensitive? All drugs can cause side effects. However, many people have no side effects or only minor side effects. Call your doctor or get medical attention if you have any side effects that bother you or don't go away. These are not all side effects that can occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects. You can report side effects to the FDA at 1-800-332-1088. You can also report side effects . If OVERDOSE is suspected: If you think you've had an overdose, call the poison control center or get medical attention right away. Be prepared to tell or show what was taken, how much, and when it happened. How to store and/or discard The PreviDent 5000 Sensitive? Store at room temperature in a dry place. Don't store it in the bathroom. Keep all the drugs in a safe place. Keep all drugs safe for children and pets. Discard unused or overdue drugs. Do not flush the toilet and drain into the sewer if you are not told to do so. Proconst with your pharmacist if you have questions about the best way to throw away drugs. There may be drug use programs in your area. Consumer Information Use If Your Symptoms or Health Problems Are Not Better, or if they get worse, call your doctor. Don't share your drugs with others and don't take other people's drugs. Some drugs may have a different patient information brochure. A proconst with your pharmacist. If you have any questions about PreviDent 5000 Sensitive (sodium fluoride and potassium nitrate), please talk to your doctor, nurse, pharmacist or other health care provider. If you think what happened call the toxicosis or get medical attention right away. Be prepared to tell or show what was taken, how much, and when it happened. For more information, contact your doctor to make sure that the information on this page is relevant to your personal circumstances. Medical Failure Read More about Prevident 5000 Sensitive (fluoride / / Nitrate Topical) Side Effects 2 Drug Reviews Class: Mouth and Throat Products Related To Treatment Guide To Prevention of Dental Tooth decay Product - Description 543-3243 Soft Mint 3.4 fl oz. (100 ml) DESCRIPTION Self-beneficial neutral fluoride dentifrik containing 1.1% (w/w) sodium fluoride and 5% potassium nitrate. INGREDIENTS Active Ingredients: Sodium fluoride 1.1% (w/w), potassium nitrate 5% Other ingredients: Purified water, moisturized silica, sorbitol, PEG-12, sodium lauryl sulfate, carrageenan, flavoring, poloxamer 407, cocameadopropil betaine, sodium saccharine, mica, sodium hydroxide, titanium dioxide, blue No.1, ORC yellow No 10 CLINICAL PHARMACOLOGY Frequent topical applications to teeth with drugs with relatively high fluoride content, increase tooth resistance to acidity and increase the resistance of teeth to acidity. INDICATION AND USAGE Dental tooth decay prophylactic and sensitive toothpaste; for twice-daily self-use of local use and then rinsing. It helps to reduce the painful sensitivity of teeth to cold, heat, acids, sweets or contacts in adult patients and children 12 years and older. PreviDent® 5000 Sensitive (Rx) brand 1.1% fluoride-containing sodium toothpaste with 5% potassium nitrate in a compression bottle is easily applied to the toothbrush. This toothpaste recipe should be used twice a day instead of your usual toothpaste, unless otherwise indicated by your dentist. It can be used in areas where drinking water is fluoridated, as topical fluoride cannot produce fluorosis (see WARNING for exclusion). CONTRAINDICATIONS Do not use in pediatric patients under the age of 12 unless recommended by a dentist or doctor. WARNING Stay out of reach of infants and children. Children under the age of 12, see a dentist or doctor. Note: Sensitive teeth may indicate a serious problem that may require prompt care from the dentist. Show the dentist if the problem persists or worsens. Do not use this product for longer than 4 weeks unless recommended by a dentist or doctor. RELATED: Not for systemic treatment. DON'T SWALLOW IT. Carcinogenesis, Mutagenes, Fertility Disorders: In a study conducted in rodents, carcinogenesis was not found in male and female mice and female rats treated with fluoride in doses of 4.1 to 9.1 mg/kg of body weight. Explicit evidence of carcinogenesis was reported in male rats treated at 2.5 and 4.1 mg/kg of body weight. In the second study, non-carcinogenesis was observed in rats, men or women treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological evidence does not provide reliable evidence of a link between fluoride, natural or added to drinking water, and the risk of human cancer. Fluoride ion is not mutagen in standard bacterial Fluoride ion has been shown cause chromosomal aberrations in human and rodent cultural cells in doses much higher than those to which humans are exposed. In vivo's data is contradictory. Some studies report damage to chromosomes in rodents, while other studies using similar protocols report negative results. The potential adverse reproductive effects of human fluoride exposure have not been properly assessed. Adverse effects were reported on the reproduction of rats, mice, foxes and cattle exposed to 100 ppm or higher concentrations of fluoride in their diet or drinking water. Other studies in rats have shown that lower concentrations of fluoride (5 mg/kg of body weight) do not lead to impaired fertility and reproductive capacity. Pregnancy - Teratogenic Effects: Pregnancy Category B. It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount injected is included in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not teratogen. Maternal exposure to body fluoride/kg (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the size of the litter or the weight of the fetus and did not increase the frequency of skeletal or visceral development. Pregnant women do not have adequate and well-controlled studies. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water have not shown an increase in birth defects. Severe exposure to fluoride during uterine development can lead to skeletal fluorosis, which becomes apparent in childhood. Nursing mothers: It is not known if fluoride is released in human milk. However, many drugs are excreted in milk, and caution should be exercised when foods containing fluoride are injected into nursing women. The decline in milk production was recorded in farm-grown foxes when the animals were fed a diet containing high concentrations of fluoride (98-137 mg/kg of body weight). No side effects on parturia, lactation or offspring were seen in rats injected with fluoride up to 5 mg/kg of body weight. Pediatric use: Safety and efficacy in pediatric patients under the age of 12 are not established. Please refer to the CONTRAINDICATIONS and WARNINGS sections. Geriatric use: Of the total number of subjects in clinical trials 1.1% (w/v) sodium fluoride, 15 percent were 65 and older, while 1 percent were 75 and older. There were no overall differences in safety or effectiveness between these subjects and young subjects, and other clinical experiences did not reveal differences in responses between older and younger patients, but the greater sensitivity of some older people could not be ruled out. This drug is known to be substantially excreted by the kidneys, and the risk reactions to this drug may be greater in patients with impaired kidney function. Because older people more likely to have reduced kidney function, care should be taken in the choice of dose, and may be useful in monitoring renal function.8 ANY REACTIONS Allergic reactions and other features have rarely been reported. OVERDOSAGE Accidental use of large amounts of fluoride can lead to acute burning in the mouth and pain in the tongue. Nausea, vomiting and diarrhea can occur shortly after meals (within 30 minutes) and are accompanied by salivation, hematemesis and epigastric cramps in the abdomen. These symptoms can persist for 24 hours. If less than 5 mg of fluoride/kg of body weight (i.e. less than 2.3 mg of fluoride/lbs. body weight) were ingested, give calcium (e.g. milk) orally to relieve gastrointestinal symptoms and observe for hours. If more than 5 mg of fluoride/kg of body weight (i.e. more than 2.3 mg of fluoride/pound body weight) were swallowed, vomited, gave oral soluble calcium (e.g. milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical attention. When taken randomly, more than 15 mg of fluoride/kg of body weight (i.e. more than 6.9 mg of fluoride/pound body weight) cause vomiting and immediately flagged to the hospital. The dose of treatment (thin tape) PreviDent® 5000 Sensitive (Rx) contains approximately 2.5 mg of fluoride. Bottle 3.38 fl. Oz. (100 ml) contains approximately 572.5 mg of fluoride. DOSAGE AND ADMINISTRATION: Follow these instructions if otherwise not to instruct your dentist: Adults and children 12 years and older: Apply at least 1 inch strip PreviDent 5000 Sensitive (Rx) to a soft toothbrush bristles. Brush your teeth thoroughly for at least 1 minute, expectorate, and rinse your mouth thoroughly. Use twice a day (morning and evening) or on the recommendation of a dentist or doctor. Make sure to clean all sensitive areas of your teeth. Children under the age of 12: See a dentist or a doctor. HOW SUPPLIED 3.4 fl. Oz. (100 ml) Plastic Bottles Soft Mint: NDC 0126-0700-61 STORAGE Store at controlled room temperature, 20-25 degrees Celsius (68-77 degrees Fahrenheit) Page 2 Product - Description 733007 Mint 3.4 fl. Oz. (100mL) plastic bottle PRESCRIBING INFORMATION DESCRIPTION Self-topical neutral fluoride-containing toothpaste containing 1.1% (w/w) sodium fluoride for use as a dental tooth decay prophylactic in adults and pediatric patients. INGREDIENTS Active Ingredient: Sodium fluoride 1.1% (w/w) Inactive Ingredients: Water, sorbitol, moisturized silicon, propylene glycol, glycerin, PEG-40 hydrogenated castor oil, phosphate dipotation, poloxamer 407, flavoring, PVM/MA copolymer, xanthan gum, sodium benzoate, sodium hydroxid, sodium saccharine, cocamidopropyl betain, cetylpiridine chloride, sorbate potassium, pectin, FD'C topical applications to teeth with relatively high fluoride fluoride content dissolving and increasing the penetration of ion fluoride into the tooth enamel. INDICATION AND USAGE Dental tooth decay prevention; this time, the daily self-use of local use. PreviDent® 5000 Dry Mouth (Rx) mark 1.1% of fluoride-containing sodium toothpaste in a compression bottle is easily applied to the toothbrush. This toothpaste recipe should be used once a day instead of your usual toothpaste unless otherwise instructed by your dental professional. It can be used in areas where drinking water is fluoridated, as topical fluoride cannot produce fluorosis. (See WARNING for exclusion.) CONTRAINDICATIONS Do not use in pediatric patients under the age of 6 unless recommended by a dentist or doctor. WARNING Long-term daily eating can lead to varying degrees of dental fluoride in pediatric patients under the age of 6, especially if water fluoridation exceeds 0.6 ppm, as young pediatric patients often cannot perform the cleaning process without significant swallowing. Use in pediatric patients under 6 years of age requires special observation to prevent re-swallowing toothpaste, which can cause dental fluorosis. Pediatric patients under the age of 12 should be monitored in the use of this product. Read the directions carefully before use. Keep infants and children out of reach. RELATED: Not for systemic treatment. DON'T SWALLOW IT. Carcinogenesis, Mutagenes, Fertility Disorders: In a study conducted in rodents, carcinogenesis was not found in male and female mice and female rats treated with fluoride in doses of 4.1 to 9.1 mg/kg of body weight. Explicit evidence of carcinogenesis was reported in male rats treated at 2.5 and 4.1 mg/kg of body weight. In the second study, non-carcinogenesis was observed in rats, men or women treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological evidence does not provide reliable evidence of a link between fluoride, natural or added to drinking water, and the risk of human cancer. Fluoride ion is not mutagen in standard bacterial systems. It has been shown that fluoride ion has the potential to cause chromosomal aberrations in cultural human and rodent cells in doses much higher than those to which humans are exposed. In vivo's data is contradictory. Some studies report damage to chromosomes in rodents, while other studies using similar protocols report negative results. The potential adverse reproductive effects of human fluoride exposure have not been properly assessed. Adverse effects were reported on the reproduction of rats, mice, foxes and cattle exposed to 100 ppm or higher concentrations of fluoride in their diet or drinking Other studies in rats have shown that lower concentrations of fluoride (5 mg/kg of body weight) do not lead to impaired fertility and reproductive capacity. Pregnancy - Teratogenic Teratogenic Category B. It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount injected is included in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not teratogen. Maternal exposure to body fluoride/kg (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the size of the litter or the weight of the fetus and did not increase the frequency of skeletal or visceral development. Pregnant women do not have adequate and well-controlled studies. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water have not shown an increase in birth defects. Severe exposure to fluoride during uterine development can lead to skeletal fluorosis, which becomes apparent in childhood. Nursing mothers: It is not known if fluoride is released in human milk. However, many drugs are excreted in milk, and caution should be exercised when foods containing fluoride are injected into nursing women. The decline in milk production was recorded in farm-grown foxes when the animals were fed a diet containing high concentrations of fluoride (98-137 mg/kg of body weight). No side effects on parturia, lactation or offspring were seen in rats injected with fluoride up to 5 mg/kg of body weight. Pediatric Use: Using PreviDent® 5000 Dry Mouth (Rx) in pediatric age groups 6 to 16 years as a prevention caries supported by groundbreaking clinical trials with 1.1% of sodium fluoride gels in mouth trays in students between the ages of 11 and 14 years, conducted by Englander eter al.6-8 Safety and Efficay in pediatric patients under 6 years of age have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections. Geriatric use: Of the total number of subjects in clinical trials 1.1% (w/v) sodium fluoride, 15 percent were 65 and older, while 1 percent were 75 and older. There were no overall differences in safety or effectiveness between these subjects and young subjects, and other clinical experiences did not reveal differences in responses between older and younger patients, but the greater sensitivity of some older people could not be ruled out. This drug is known to be substantially excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired kidney function. Because older patients are more likely to have reduced kidney function, care should be taken in choosing a dose, and this may be useful for monitoring kidney function.9 UNSAPFUL Reactions and other features have been rarely reported. OVERDOSAGE Accidental use of large amounts of fluoride can lead to acute burning in the mouth and pain in the tongue. Nausea, vomiting and diarrhoea can occur shortly after eating (within 30 minutes) and are accompanied by salivation, and epigastric spasm in the abdomen These symptoms can persist for 24 hours. If less than 5 mg of fluoride/kg of body weight (i.e. less than 2.3 mg of fluoride/lbs. body weight) were ingested, give calcium (e.g. milk) orally to relieve gastrointestinal symptoms and observe for hours. If more than 5 mg of fluoride/kg of body weight (i.e. more than 2.3 mg of fluoride/pound body weight) were swallowed, vomited, gave oral soluble calcium (e.g. milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical attention. When taken randomly, more than 15 mg of fluoride/kg of body weight (i.e. more than 6.9 mg of fluoride/pound body weight) cause vomiting and immediately flagged to the hospital. The dose of treatment (thin tape) PreviDent® 5000 Dry Mouth (Rx) contains approximately 2.5 mg of fluoride. A bottle of FL O'o (100 ml) contains about 610 mg of fluoride. DOSAGE AND ADMINISTRATION Follow these instructions unless otherwise prescribed by your dentist: Adult and pediatric patients 6 years and older, apply a thin tape PreviDent® 5000 dry mouth (Rx) on the toothbrush. Brush thoroughly once a day for two minutes, preferably before bedtime, instead of regular toothpaste. After use, adults expectorate. For best results, don't eat, drink or rinse for 30 minutes. Pediatric patients aged 6-16 years expect after use and carefully rinse their mouths. HOW 3.4 fl. Oz. (100 ml) in plastic bottles Soothing Mint: NDC 0126-0016-61 STORAGE Store at controlled room temperature, 20-25 degrees Celsius (68-77 degrees Fahrenheit) Page 3 Product - Description 733013 Mint: 1.8 oz (51g) tube 733014 Spiermint: double pack, double pack, Two 1.8 oz (51g) tubes 733015 Fruitastic-™: 1.8 oz (51g) tube PRESCRIBING UPDATE Self-topical neutral fluoride dentifrick containing 1.1% (w/w) sodium fluoride for use as dental tooth decay prevention in adults and pediatric patients. ACTIVE INGREDIENTS Sodium fluoride 1.1% (w/w) OTHER INGREDIENTS Purified water, sorbitol, moisturized silica, PEG-12, tetrapotassium pyrophosphate, sodium sulfuric launit, mint aroma (mint flavor only), xanthan gum, sodium benzoate, fruity taste (only fruit™ taste), sodium saccharine, titanium dioxide (only fruit™ taste), FD'C Blue #1 (mint only), D'C Red #33 (Fruitastic™' flavor) CLINICAL CLINICAL CLINICALY Frequent topical applications to drugs with relatively high content of fluoride, increase the resistance to the teeth. INDICATION AND USAGE Dental tooth decay prevention; this time, the daily self-use of local use. It is well known that 1.1% of sodium fluoride is safe and extremely effective as a prevention of caries when often used with a mouthpiece 5000 Plus (Rx) brand 1.1% sodium fluoride in compression tube easily applied on Toothbrush. This dental cream recipe should be used once a day instead of your usual toothpaste unless otherwise instructed by your dental professional. It can be used in areas where drinking water is fluoridated, as topical fluoride cannot produce fluorosis. (See WARNING below for exclusion.) CONTRAINDICATIONS Do not use in pediatric patients under the age of 6 unless recommended by a dentist or doctor. WARNING Long-term daily eating can lead to varying degrees of dental fluoride in pediatric patients under the age of 6, especially if water fluoridation exceeds 0.6 ppm, as young pediatric patients often cannot perform the cleaning process without significant swallowing. Use in pediatric patients under 6 years of age requires special monitoring to prevent the re-swallowing of dental cream, which can cause dental fluorosis. Read the directions carefully before use. Keep infants and children out of reach. RELATED: Not for systemic treatment. DON'T SWALLOW IT. Carcinogenesis, Mutagenes, Fertility Disorders: In a study conducted in rodents, carcinogenesis was not found in male and female mice and female rats treated with fluoride in doses of 4.1 to 9.1 mg/kg of body weight. Explicit evidence of carcinogenesis was reported in male rats treated at 2.5 and 4.1 mg/kg of body weight. In the second study, non-carcinogenesis was observed in rats, men or women treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological evidence does not provide reliable evidence of a link between fluoride, natural or added to drinking water, and the risk of human cancer. Fluoride ion is not mutagen in standard bacterial systems. It has been shown that fluoride ion has the potential to cause chromosomal aberrations in cultural human and rodent cells in doses much higher than those to which humans are exposed. In vivo's data is contradictory. Some studies report damage to chromosomes in rodents, while other studies using similar protocols report negative results. The potential adverse reproductive effects of human fluoride exposure have not been properly assessed. Adverse effects were reported on the reproduction of rats, mice, foxes and cattle exposed to 100 ppm or higher concentrations of fluoride in their diet or drinking water. Other studies in rats have shown that lower concentrations of fluoride (5 mg/kg of body weight) do not lead to impaired fertility and reproductive capacity. Pregnancy: It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount injected is included in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not teratogen. Maternal exposure to body fluoride/kg (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the size of the litter or the weight of the fetus and did not increase frequency of skeletal or visceral malformations. Pregnant women do not have adequate and well-controlled studies. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water have not shown an increase in birth defects. Severe exposure to fluoride during uterine development can lead to skeletal fluorosis, which becomes apparent in childhood. Nursing mothers: It is not known if fluoride is released in human milk. However, many drugs are excreted in milk, and caution should be exercised when foods containing fluoride are injected into nursing women. The decline in milk production was recorded in farm-grown foxes when the animals were fed a diet containing high concentrations of fluoride (98-137 mg/kg of body weight). No side effects on parturia, lactation or offspring were seen in rats injected with fluoride up to 5 mg/kg of body weight. Pediatric use: The use of PreviDent 5000 Plus (Rx) in pediatric groups between the ages of 6 and 16 as a prevention of kari is supported by innovative clinical studies with 1.1% of sodium fluoride gels in oral trays in students aged 11 to 14 years conducted by Englander eter. 5-7 Safety and efficacy in pediatric patients under 6 years of age is not established. Please refer to the CONTRAINDICATIONS and WARNINGS sections. RELATED REACTIONS Accidental use of large amounts of fluoride can lead to acute burning in the mouth and pain in the tongue. Nausea, vomiting and diarrhea can occur shortly after meals (within 30 minutes) and are accompanied by salivation, hematemesis and epigastric cramps in the abdomen. These symptoms can persist for 24 hours. If less than 5 mg of fluoride/kg of body weight (i.e. less than 2.3 mg of fluoride/lbs. body weight) were ingested, give calcium (e.g. milk) orally to relieve gastrointestinal symptoms and observe for hours. If more than 5 mg of fluoride/kg of body weight (i.e. more than 2.3 mg of fluoride/pound body weight) were swallowed, vomited, gave oral soluble calcium (e.g. milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical attention. When taken randomly, more than 15 mg of fluoride/kg of body weight (i.e. more than 6.9 mg of fluoride/pound body weight) cause vomiting and immediately flagged to the hospital. PreviDent 5000 Plus (Rx) contains 2.5 mg of fluoride. The 1.8 ounce tube contains 255 mg of fluoride. DOSAGE AND ADMINISTRATION Follow these instructions if otherwise not instructing your dentist: Adult and pediatric patients ages 6 and over: Apply a thin Tape PreviDent 5000 Plus (Rx) to your toothbrush. Brush thoroughly once a day for two minutes, preferably before bedtime. After use, adults expectorate. For the best Do not eat, drink or rinse for 30 minutes. Pediatric patients aged 6-16, expect after use and rinse rinse Carefully. HOW supplied 1.8 oz. (51g) net wt. Spearmint Tube - NDC 0126-0287-66 Fruitastic™ - NDC 0126-0288-66 Twin Pack (two 1.8 ounces. (51g) net wt. Tube) Mint - NDC 0126-0287-33 STORAGE Store at controlled room temperature, 20-25 degrees Celsius (68-77 degrees Fahrenheit). Page 4 Product - Description 733101 Mint 3.4 fl. Oz. (100 ml) 733100 Fruitastic™ 3.4 fl. Oz. (100 mL) PRESCRIBING INFORMATION DESCRIPTION Self-topical neutral fluoride dentifrice containing 1.1% (w/w) sodium fluoride for use as a prevention of tooth decay in adult and pediatric patients. INDICATION AND USAGE Dental tooth decay prevention; this time, the daily self-use of local use. PreviDent® 5000 Booster Plus brand 1.1% fluoride-containing sodium toothpaste in a compression bottle is easily applied to the toothbrush. This toothpaste recipe should be used once a day instead of your usual toothpaste unless otherwise instructed by your dental professional. It can be used in areas where drinking water is fluoridated, as topical fluoride cannot produce fluorosis. (See WARNING for exclusion). CONTRAINDICATIONS Do not use in pediatric patients under the age of 6 unless recommended by a dentist or doctor. WARNING Long-term daily eating can lead to varying degrees of dental fluoride in pediatric patients under the age of 6, especially if water fluoridation exceeds 0.6 ppm, as young pediatric patients often cannot perform the cleaning process without significant swallowing. Use in pediatric patients under 6 years of age requires special observation to prevent re-swallowing toothpaste, which can cause dental fluorosis. Pediatric patients under the age of 12 should be monitored in the use of this product. Read the directions carefully before use. Keep infants and children out of reach. RELATED: Not for systemic treatment. DON'T SWALLOW IT. Carcinogenesis, Mutagenes, Fertility Disorders: In a study conducted in rodents, carcinogenesis was not found in male and female mice and female rats treated with fluoride in doses of 4.1 to 9.1 mg/kg of body weight. Explicit evidence of carcinogenesis was reported in male rats treated at 2.5 and 4.1 mg/kg of body weight. In the second study, non-carcinogenesis was observed in rats, men or women treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological evidence does not provide reliable evidence of a link between fluoride, natural or added to drinking water, and the risk of human cancer. Fluoride ion is not mutagen in standard bacterial systems. It has been shown that fluoride ion has the potential to cause chromosomal aberrations in cultural human and rodent cells in doses much higher than those to people are exposed. In vivo's data is contradictory. Some studies report damage to chromosomes in rodents, while other studies using similar protocols report negative results. Potential Potential reproductive effects of fluoride in humans were not properly assessed. Adverse effects were reported on the reproduction of rats, mice, foxes and cattle exposed to 100 ppm or higher concentrations of fluoride in their diet or drinking water. Other studies in rats have shown that lower concentrations of fluoride (5 mg/kg of body weight) do not lead to impaired fertility and reproductive capacity. Pregnancy: Teratogenic Effects: Pregnancy Category B. It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount injected is included in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not teratogen. Maternal exposure to body fluoride/kg (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the size of the litter or the weight of the fetus and did not increase the frequency of skeletal or visceral development. Pregnant women do not have adequate and well-controlled studies. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water have not shown an increase in birth defects. Severe exposure to fluoride during uterine development can lead to skeletal fluorosis, which becomes apparent in childhood. Nursing mothers: It is not known if fluoride is released in human milk. However, many drugs are excreted in milk, and caution should be exercised when foods containing fluoride are injected into nursing women. The decline in milk production was recorded in farm-grown foxes when the animals were fed a diet containing high concentrations of fluoride (98-137 mg/kg of body weight). No side effects on parturia, lactation or offspring were seen in rats injected with fluoride up to 5 mg/kg of body weight. Pediatric Use: Using PreviDent® 5000 Booster Plus in pediatric age groups 6 to 16 years as a prevention caries supported by innovative clinical studies with 1.1% of sodium fluoride gels in mouth trays in students aged 11 to 14 years, conducted by Englander et al.4-4 Safety and efficacy in pediatric patients under 6 years of age have not been established. Please refer to the CONTRAINDICATIONS and WARNINGS sections. Geriatric use: Of the total number of subjects in clinical trials 1.1% (w/v) sodium fluoride, 15 percent were 65 and older, while 1 percent were 75 and older. There were no overall differences in safety or effectiveness between these subjects and young subjects, and other clinical experiences did not reveal differences in responses between older and younger patients, but the greater sensitivity of some older people could not be ruled out. This drug is known to be significantly excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impairments Kidney. Because older patients are more likely to have declined Function care should be taken in the selection of doses, and it may be useful to monitor kidney function.5 Adverse reactions reactions to allergic reactions and other features have been rarely reported. OVER DOSAGE Accidental use of large amounts of fluoride can lead to acute burning in the mouth and pain in the tongue. Nausea, vomiting and diarrhea can occur shortly after meals (within 30 minutes) and are accompanied by salivation, hematemesis and epigastric cramps in the abdomen. These symptoms can persist for 24 hours. If less than 5 mg of fluoride/kg of body weight (i.e. less than 2.3 mg of fluoride/lbs of body weight) was ingested, give calcium (e.g. milk) orally to relieve gastrointestinal symptoms and observe for hours. If more than 5 mg of fluoride/kg of body weight (i.e. more than 2.3 mg of fluoride/pound body weight) enters the body) enters the body, causes vomiting, gives oral soluble calcium (e.g. milk, 5% calcium gluconate or calcium lactate solution) and seek immediate medical attention. When taken randomly, more than 15 mg of fluoride/kg of body weight (i.e. more than 6.9 mg of fluoride/pound body weight) cause vomiting and immediately flagged to the hospital. DOSAGE AND ADMINISTRATION: Follow these instructions, unless otherwise instructing your dentist: Adult and pediatric patients ages 6 and older, apply a thin Tape PreviDent® 5000 Booster Plus on your toothbrush. Brush your teeth carefully once a day for two minutes, preferably before bedtime, instead of regular toothpaste. After use, adults expectorate. For best results, don't eat, drink or rinse for 30 minutes. Pediatric patients, aged 6-16 years, expect after use and thoroughly rinse their mouths. Reverend 07/12 HOW TO PUT 3.4 fl. Oz. (100 ml) in Spearmint plastic bottles: NDC 0126-0075-92 Fruitastic: NDC 0126-0076-92 STORAGE Store at controlled room temperature, 20-25 degrees Celsius (68-77 degrees Fahrenheit) open source annotation tool nlp. best open source annotation tools for computer vision. image annotation tool open source. open source text annotation tool. open source video annotation tool. open source pdf annotation tool. prodigy annotation tool open source. open source data annotation tools

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