NEUTRAMAXX 5000 TRI-CALCIUM PHOSPHATE- sodium fluoride paste, dentifrice
Massco Dental A Division of Dunagin Pharmaceuticals

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.

NeutraMaxx TCP 502 - Vanilla Mint

Drug Facts
Active Ingredients

1.1 % Neutral Sodium Floride

DESCRIPTION:

Self-topical neutral fluoride dentifrice containing 1.1%(w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Purpose

For prevention of tooth decay, orthodontic decalcification and hypersensitivity.

Keep Out of Reach of Children.

As with all medications, keep out of reach of children.

CLINICAL PHARMACOLOGY:

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

INDICATIONS AND USAGE:

NeutraMaxx™ 5000 with Tri-Calcium Phosphate is a self applied dentifrice for prevention of tooth decay, orthodontic decalcification and hypersensitivity

A dental caries preventive; for once daily self-applied topical use. 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 NeutalMaxx™ brand of 1.1% sodium fluoride in a squeeze tube is easily applied onto a toothbrush. This prescription dental cream should be used once daily in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used whether or not drinking water is fluoridated, since topical fluoride cannot produce fluorisis. (See WARNINGS for exceptions)

WARNINGS:

Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under 6 years, especially if the water fluoridation exceeds 0.6 ppm, since younger pediatric patients frequently cannot preform the brushing process without significant swallowing. Use in pediatric patients under 6 years requires special supervision to prevent repeated swallowing of the cream which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

Warnings

- Do not swallow
- For topical use only
- As with all medications, keep out of reach of children

PRECAUTIONS:

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 carcinogensesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of boby weight. Epidemiological data provide no credible evidence for an assocoation between Fluoride, either naturally occuring or added to drinking water, and the 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. Invivo data 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 (5mg/kg of body weight) do not resule in impaired fertility and reproductive capabilities.

Pregnancy:

Pregnancy Catagory B. It has shown that fluoride crosses the placenta of rats, bot only 0.01% of the amount administered in 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 body weight (rabbits) did not affect the litter size of fetal weight and did not increase the frequency of sheletal or visceral malformations. Epidemiologiical studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. heavy exposure to fluoride during 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 product 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 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 NeutraMaxx™ in pediatric age group 6 to 16 years as a caries preventive is supported by pioneering clinical studies with 1.1% sodium Fluoride gets 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 **CONTRAINDICATIONS** and **WARNINGS** sections.

ADVERSE REASTIONS:

Allergic reaction and other idosyncrasies have been rarely reported.

OVERDOSE:

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

DOSAGE AND ADMINISTRATION:
Directions: Use As Directed

This prescription dentifrice is recommended for adults and pediatric patients 6 years and older

- Apply a thin ribbon of NeutraMaxxtm 5000 TCP along the length of the toothbrush no more than "pea size" total dose. Brush for two minutes.
- After brushing ADULTS - Expectorate, do not eat for 30 minutes. CHILDREN 6 YEARS OF AGE OR OLDER - Expectorate and rinse mouth with water. Rinse mouth thoroughly.
- Use at bedtime in place of your regular toothpaste or as directed by your dental professional.

Follow these instructions unless otherwise instructed by you dental professional.

HOW SUPPLIES:

4 oz. (112 gm) net wt. tube

STORAGE:

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

Inactive Ingredients:

Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG 8000, Carboxymethylcellulose, Xylitol, MonoSodium Phosphate, Titanium Dioxide, Vanilla Mint Flavor, Sodium Saccharin, Tri-Calcium Phosphate

Questions? Comments? Section

Call 1-479-787-5168 M-F 9am to 5 pm CST

NeutraMaxxC TCP VANILLA MINT

NDS 63783 63783-502-04

VANILLA MINT FLAVOR

ANTI-CAVITY TOOTHPASTE XYLITOL

NeutraMaxx™

5000 TRI-CALCIUM PHOSPHATE

1.1% Neutral Sodium Fluoride 5000 ppm

Sweetened with Xylitol

DOES NOT CONTAIN SODIUM LAURYL SULFATE

RX ONLY

Net wt. 4 oz (112 G)

Manufactured By:

MASSCO DENTAL

A Division of Dunagin Pharmaceuticals,

Rogers, AR

800-227-1296 • www.masscodental.net

VANILLA MINT FLAVOR
RELIEVES SENSITIVITY

XYLITOL

ANTI-CAVITY TOOTHPASTE

NeutraMaxx™
5000 TRI-CALCIUM PHOSPHATE

Drug Facts

Active Ingredient
1.1% Neutral Sodium Fluoride

Inactive Ingredients: Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG 8000, Carboxymethylcellulose, Xylitol, Monosodium Phosphate, Titanium Dioxide, Vanilla Mint Flavor, Sodium Saccharin, Tri-Calcium Phosphate

Indications
NeutraMaxx™ 5000 with Tri-Calcium Phosphate is a self-applied dentifrice for prevention of tooth decay, orthodontic decalcification and hypersensitivity.

Warnings

- **Do not swallow**
- **For topical use only**
- **As with all medications, keep out of reach of children**

Directions: Use As Directed

This prescription dentifrice is recommended for adults and pediatric patients 6 years and older.

- Apply a thin ribbon of NeutraMaxx™ 5000 Tri-Calcium Phosphate along the length of the toothbrush no more than "pea size" total dose. Brush for two minutes.
- After brushing:
  ADULTS-Expectorate; do not eat or drink for 30 minutes.
  CHILDREN 6 YEARS OF AGE OR OLDER-Expectorate and rinse mouth with water.
- Use at bedtime in place of your regular toothpaste or as directed by your dental professional.

Questions? Comments?

Call us at 800-227-1296
M-F 9am to 5pm CST

1.1% Neutral Sodium Fluoride 5000 ppm
Sweetened with Xylitol
DOES NOT CONTAIN
SODIUM LAURYL SULFATE

Rx ONLY

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A Division of Dunagin
Pharmaceuticals, Rogers, AR
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Net Wt. 4 oz. (112 G)

NeutraMaxx™ 5000 1.1% Sodium Fluoride Prescription Dental Cream

DESCRIPTION: Self-topical neutral fluoride dentifrice containing 1.1%(w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.
Active Ingredients: Neutral Sodium Fluoride 1.1 %(w/w)
Inactive Ingredients: Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG 8000, Carboxymethylcellulose, Xylitol, Monosodium Phosphate, Titanium Dioxide, Mint Flavor, Sodium Saccharin, Tri-Calcium Phosphate.
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 is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators. 1-4 NeutraMaxx™ brand of 1.1% sodium fluoride in a squeeze tube is easily applied onto a toothbrush. This prescription dental cream should be used once daily in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used whether or not drinking water is fluoridated, since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)
CONTRA INDICATIONS: 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 6 years, especially if the water fluoridation exceeds 0.6 ppm, since younger pediatric patients frequently cannot preform the brushing process without significant swallowing. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of the cream which could cause dental fluorosis. Read directions carefuily before using. Keep out of reach of infants and children.
PRECAUTIONS: Not for systematic 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 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 (5mg/kg of body weight) did not result in impaired fertility and reproductive capabilities.
Pregnancy: Pregnancy Category B. It has 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 of fetal weight and did not increase the frequency of skeletal or visceral malformations. Epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects, Heavy exposure to fluoride during 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 product 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 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 NeutraMaxx™ 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 **CONTRA INDICATIONS** and **WARNINGS** sections.
ADVERSE REACTIONS: Allergic reaction and other idiosyncrasies have been rarely reported.
OVERDOSAGE: Accidental ingestion of large amounts of fluoride may result in acute burning of 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 of body weight (i.e., less than 2.3 mg fluoride/lb. body weight) have been ingested, give calcium (e.g., milk) orally to relive 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 emesis, 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.
DOSAGE AND ADMINISTRATION: Follow these instructions unless otherwise instructed by your dental professional: 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of NeutraMaxx™ to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime. 2. After use, adults expectorate. For best results, do not eat, drink or rinse for 30 minutes. Pediatric patients, age 6-16, expectorate after use and rinse mouth thoroughly.
HOW SUPPLIES: 4 oz. (112 gm) net wt. tube
STORAGE: Store at controlled room temperature, 20-25°C (68-77°F).
Rx Only
REFERENCES: 1. Accepted Dental Therapeutics. Ed 40, ADA. Chicago. PA05-407, 1984. 2. Englander HR, Keyes et al: JADA 75:638-644, 1967. 3. Englander HR, et al: JADA 78:783-787, 1969. 4. Englander HR, et al: JADA 83:354-358. 1971.

Manufactured by MASSCO DENTAL, A division of Dunagin Pharmaceuticals, Rogers, AR 72758, www.masscodental.net

NEUTRAMAXX 5000 TRI-CALCIUM PHOSPHATE

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63783-502
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	VANILLA (VANILLA MINT)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-502-04	112 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Registrant - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Establishment

Name	Address	ID/FEI	Business Operations
Massco Dental A Division of Dunagin Pharmaceuticals		008081858	manufacture(63783-502)

Revised: 12/2023 Massco Dental A Division of Dunagin Pharmaceuticals