

NEUTRAMAXX 5000 TCP- 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.

Active Ingredient Section

DRUG FACTS ACTIVE INGREDIENT 1.1 % NEUTRAL SODIUM FLUORIDE

Purpose Section

For prevention of tooth decay, orthodontic decalcification and hypersensitivity.

Keep Out of Reach of Children Section

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

Indications and Usage Section

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

Warning Section

Warnings Do not swallow For topical use only

Directions: Use As Directed Section

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. Use at bedtime in place of your regular toothpaste or as directed by your dental professional.

Inactive Ingredient Section

Inactive Ingredients: Deionized Water, Sorbitol, Hydrated Silica, PEG, Carboxymethylcellulose, Xylitol, MonoSodium Phosphate, Titanium Dioxide, Mint Flavor, Sodium Saccharin, Tri-Calcium Phosphate

Questions? Comments? Section

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

Package Label

REFRESHING MINT FLAVOR RELIEVES SENSITIVITY

ANTI-CAVITY TOOTHPASTE NeutraMaxx tm 5000 TCP XYLITO1.1% 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, Gravette, AR (479) 787-5168 www.masscodental.net



NDC 63783-501-04

REFRESHING MINT FLAVOR
RELIEVES SENSITIVITY



ANTI-CAVITY TOOTHPASTE

NeutraMaxxTM
5000 TCP

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

Rx ONLY

Drug Facts

Active Ingredients:
1.1% Neutral Sodium Fluoride.
Inactive Ingredients:

Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG 8000, Carboxymethylcellulose, Xylitol, Monosodium Phosphate, Titanium Dioxide, Mint Oil Type-P, Sodium Saccharin, Tri-Calcium Phosphate.

Indications

NeutraMaxxTM 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 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 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.

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REFRESHING MINT FLAVOR
RELIEVES SENSITIVITY



ANTI-CAVITY TOOTHPASTE

NeutraMaxxTM
5000 TCP

1.1% Neutral Sodium Fluoride 5000 ppm
Sweetened with Xylitol
**DOES NOT CONTAIN
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Rx ONLY

Net Wt. 4 oz. (112 G)

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res

NEUTRAMAXX 5000 TCP

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63783-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.1 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
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	MINT (REFRESHING MINT FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-501-04	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(63783-501)

Revised: 12/2023

Massco Dental A Division of Dunagin Pharmaceuticals