

**SODIUM FLUORIDE- sodium fluoride paste, dentifrice**  
**Safco Dental Supply LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----  
**DRUG FACTS**

**Active ingredient:**

Sodium fluoride - 0.243% (0.15% w/v Fluoride ion)

**Purpose:**

Anti-cavity

**Use:**

Helps protect against cavities

**Warning:**

KEEP OUT OF THE REACH OF CHILDREN UNDER 6 YEARS OF AGE. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.

**Directions:**

Adults and Children 6-years of age and older

Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.

Children 2 to 6 years

Use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years

Ask a dentist or a physician

**Other ingredients:**

Sorbitol, Silica, Treated Water, Poly Ethylene Glycol 1500, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose gum and/or Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Tetra Sodium Pyrophosphate, Glycerin, Color: FD&C Blue #1

Package date and batch number on crimp.

## Principal Display Panel - 24 g Box Label

**Quantum Fresh**  
FLUORIDE TOOTHPASTE

**Quantum**

a **safco** company

**800-328-8213**

www.QuantumLabs.com

Fluoride Toothpaste

Reorder # 826-0001

Net Wt. 0.85 oz (24 g)

Expiration Date:

2 years from date  
packed.

NDC 67239-0226-0

Made in India

**Quantum Fresh**  
FLUORIDE TOOTHPASTE

<b>DRUG FACTS</b>	
Active ingredient: Sodium fluoride - 0.243% (0.15% w/v Fluoride ion)	Purpose: Anti-cavity
Use: Helps protect against cavities	
Warning: KEEP OUT OF THE REACH OF CHILDREN UNDER 6 YEARS OF AGE. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.	
Directions: Adults and Children 6-years of age and older	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician.
Children 2 to 6 years	Use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)
Children under 2 years	Ask a dentist or a physician
Other ingredients: Sorbitol, Silica, Treated Water, Poly Ethylene Glycol 1500, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose gum and/or Carrageenan, Trisodium Orthophosphate, Sodium Saccharin, Tetra Sodium Pyrophosphate, Glycerin, Color: FD&C Blue #1	
Package date and batch number on crimp.	

**Quantum**  
a **safco** company

**800-328-8213**

www.QuantumLabs.com

Fluoride Toothpaste

Reorder # 826-0001

Net Wt. 0.85 oz (24 g)

Expiration Date:

2 years from date  
packed.

NDC 67239-0226-0

Made in India



## SODIUM FLUORIDE

sodium fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67239-0226
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.43 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 1500</b> (UNII: 1212Z7S33A)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BUTYL ESTER OF METHYL VINYL ETHER/MALEIC ANHYDRIDE COPOLYMER (125000 MW)</b> (UNII: 389H2R62BD)	
<b>SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE</b> (UNII: B70850QPHR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>TRICLOSAN</b> (UNII: 4NM5039Y5X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67239-0226-0	24 g in 1 TUBE; Type 0: Not a Combination Product	04/24/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	04/24/2023	

**Labeler** - Safco Dental Supply LLC (020417380)

Revised: 3/2023

Safco Dental Supply LLC