

**CLOSEUP TRAVEL- sodium fluoride paste, dentifrice
GURUNANDA, 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.

CLOSEUP TOOTHPASTE 79 GM

ACTIVE INGREDIENTS

Sodium Fluoride 0.21%

PURPOSE

Anticavity

USE

Aids in the prevention of dental cavities

WARNING

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children under 6 years of age.

DIRECTIONS

Do not swallow.

- Adults and children 2 years and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- Children under 6 Years of Age: Use only a pea-sized amount and supervise children's brushing and rinsing to minimize swallowing.
- Children under 2 years of age: Ask a dentist or physician

INACTIVE INGREDIENTS

Sorbitor, Water, Silica, Sodium Lauryl Sulfate, PEG-32, Titanium Dioxide, Flavor, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Zinc Sulfate, Sodium Hydroxide, D&C Red 33, FD&C Red 40, Synthetic Fluorophlogopite, Melaleuca Alternifolia

(Tea Tree Extract), Eucalyptus Globulus (Eucalyptus Extract), Eugenol
 1-866-421-0309

PRINCIPAL DISPLAY PANEL



CLOSE-UP
TRAVEL KIT
 TOOTHBRUSH+COVER+TOOTHPASTE

TOOTHBRUSH COVER
 TOOTHBRUSH
 TOOTHPASTE

DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
Sodium fluoride 0.21%	Anticavity
USE Aids in the prevention of dental cavities	
WARNING: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
Directions: ■ Do not swallow	
ADULTS & CHILDREN 2 YEARS OF AGE & OLDER Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.	
CHILDREN UNDER 6 YEARS OF AGE Use only a pea-sized amount and supervise child's brushing and rinsing to minimize swallowing.	
CHILDREN UNDER 2 YEARS OF AGE Ask a dentist or physician.	
INACTIVE INGREDIENTS: Sorbitol, Water, Silica, Sodium Lauryl Sulfate, PEG-32, Flavor, Cellulose Gum, Cocamidopropyl Betaine, Sodium Saccharin, Zinc Sulfate, Sodium Hydroxide, Titanium Dioxide (CI77891), D&C Red 33 (CI17200), Synthetic Fluorophlogopite, FD&C Red 40 (CI16035), Melaleuca Alternifolia (Tea Tree Extract), Eucalyptus Globulus (Eucalyptus Extract), Eugenol	
QUESTIONS OR COMMENTS? 1-866-421-0309 OR CONTACT@GURUNANDA.COM	
LOT : 006222ER0001 EXPIRY : 12/2023	
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10-26-000-08182-1  8 1005108182 MADE IN INDIA 10-75-000-08182-1 V08182B	

CLOSEUP TRAVEL

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70708-182
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.21 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS GLOBULUS WHOLE (UNII: S11P2XF3M3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
EUGENOL (UNII: 3T8H1794QW)	
MELALEUCA ALTERNIFOLIA WHOLE (UNII: 976KV4FXYP)	
SODIUM SILICATE (UNII: IJF18F77L3)	
ZINC SULFATE (UNII: 89DS0H96TB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALPHA CELLULOSE (UNII: I355QGZ19A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PEG-32 LAURATE (UNII: F8XJF81O0F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70708-182-01	1 in 1 POUCH	08/01/2022	
1	NDC:70708-182-80	80 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/01/2022	

