

CLOSE UP TRAVEL- sodium fluoride paste, dentifrice
JHS SVENDGAARD LABORATORIES LIMITED

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.

72025-004

Active Ingredient

Sodium Fluoride 0.21%

Purpose:

Anticavity

Uses:

Aids in the prevention of dental cavities

Warnings:

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 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:

Sorbitol, 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



CLOSE·UP[®]

TRAVEL KIT

TOOTHBRUSH+COVER+TOOTHPASTE

TOOTHBRUSH COVER
TOOTHBRUSH
TOOTHPASTE

DRUG FACTS

ACTIVE INGREDIENT

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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

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MADE IN INDIA

10-75-000-08182-1
V08182B

CLOSE UP TRAVEL

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72025-004
Route of Administration	ORAL		

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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALPHA CELLULOSE (UNII: I355QGZ19A)	
SODIUM SILICATE (UNII: IJF18F77L3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PEG-32 LAURATE (UNII: F8XJF81O0F)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
ZINC SULFATE (UNII: 89DS0H96TB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MELALEUCA ALTERNIFOLIA WHOLE (UNII: 976KV4FXYP)	
EUCALYPTUS GLOBULUS WHOLE (UNII: SI1P2XF3M3)	
EUGENOL (UNII: 3T8H1794QW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72025-004-01	79 g in 1 TUBE; Type 0: Not a Combination Product	12/27/2021	
2	NDC:72025-004-02	24 g in 1 TUBE; Type 0: Not a Combination Product	12/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/27/2021	

Labeler - JHS SVENDGAARD LABORATORIES LIMITED (675939900)

Establishment

Name	Address	ID/FEI	Business Operations
JHS SVENDGAARD LABORATORIES LIMITED		675939900	manufacture(72025-004)

Revised: 8/2022

JHS SVENDGAARD LABORATORIES LIMITED