THERABREATH FRESH BREATH- sodium fluoride paste, dentifrice
Dr. Harold Katz, 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.

TheraBreath Fresh Breath

Active Ingredients

Sodium Fluoride 0.24%

(0.14% W/V fluoride ion)

Purpose

Anticavity Fluoride Dentrifice

Uses

Aids in the prevention of dental cavities

Directions

Adults & Children 2 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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

Warnings

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

Warnings

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

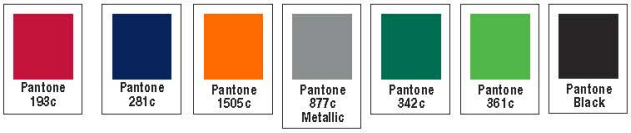
Other information

- If spilled on fabrics, wash out immediately.
- This product was sealed with protective packaging at the laboratory.
- If seal is missing, do not use.

Inactive Ingredients

Sorbitol, Water (Aqua), Hydrated Silica, Glycerin (from vegetable sources), Xylitol, Natural Flavor, Cellulose Gum, Tetrapotassium Pyrophosphate, Tetrasodium Pyrophosphate, Sodium Benzoate, Aloe Barbadensis Leaf Juice, Citric Acid, Sodium Chlorite (OXYD-8™), Ammonium Glycyrrhizate, Ascorbic Acid (Vitamin C), Mentha Arvensis (Cornmint) Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Natural Fragrance (Parfum)

TheraBreath Fresh Breath



Outer Packaging Box

Mild Mint Travel Size

THERABREATH FRESH BREATH

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72551-250
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0024 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
SPEARMINT (UNII: J7I2T6IV1N)	
MENTHA ARVENSIS FLOWER OIL (UNII: Q129Z1W6Y2)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
SODIUM CHLORITE (UNII: G538EBV4VF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (Clear)	**Score**	
Shape		**Size**	
Flavor	MINT (Mild Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-250-01	1 in 1 PACKAGE	10/04/2018	
1		113.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72551-250-02	21.3 g in 1 TUBE; Type 0: Not a Combination Product	10/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/04/2018	

Labeler - Dr. Harold Katz, LLC (965507767)

Revised: 2/2022 Dr. Harold Katz, LLC