

**ORBITOL MINT FLAVORED FLUORIDE TOOTHPASTE- sodium monofluorophosphate paste
tropical degil cosmetics industries ltd**

Orbitol Mint Flavored Fluoride Toothpaste

Active ingredient

Sodium monofluorophosphate 1.1% w/w (1450 ppm fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Do not use

Do not use if you are sensitive to any of the ingredients in this product.

When using this product

When using this product avoid contact with eyes.

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

- **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 doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- **Children under 6 years of age:** Do not use unless directed by a dentist or doctor.

Inactive ingredients

sorbitol, water, calcium carbonate, silica, cellulose gum, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate, benzoic acid, limonene.

Other information

Other information store below 30°C (86°F).

Principal Display Panel



ORBITOL MINT FLAVORED FLUORIDE TOOTHPASTE

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62685-231
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62685-231-04	1 in 1 BOX	09/27/2021	
1		145 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/27/2021	

Labeler - tropical degil cosmetics industries ltd (600437230)

Establishment

Name	Address	ID/FEI	Business Operations
tropical degil cosmetics industries ltd		600437230	manufacture(62685-231)

Revised: 3/2024

tropical degil cosmetics industries ltd