

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

*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.*

-----

**Orbitol Whitening**

**Active ingredient**

Sodium monofluorophosphate 0.8% w/w (1000 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**

water, sorbitol, calcium carbonate, silica, peg-32, cellulose gum, sodium lauryl sulfate, sodium bicarbonate, flavor, titanium dioxide, sodium saccharin, sodium benzoate, menthyl lactate, benzoic acid, zinc citrate, limonene

## Other information

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

## Principal Display Panel



## ORBITOL FLUORIDE WHITENING TOOTHPASTE

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62685-232
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.8 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>ZINC CITRATE</b> (UNII: K72I3DEX9B)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62685-232-04	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 final	part355	09/27/2021	

**Labeler** - tropical degil cosmetics industries ltd (600437230)

## Establishment

Name	Address	ID/FEI	Business Operations
tropical degil cosmetics industries ltd		600437230	manufacture(62685-232)

Revised: 1/2023

tropical degil cosmetics industries ltd