ORAL PROJEQT O1 TOOTHPASTETABLETS- sodium fluoride tablet
Sungwon Pharmaceutical Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

Silicon Dioxide, Tetrasodium Pyrophosphate, Pyridoxine Hydrochloride, Sodium Fluoride

INACTIVE INGREDIENT

D-Sorbitol, Microcrystalline Cellulose, Sodium Chloride, Xylitol, Enzymatically Modified Stevia, Sodium Cocoyl Glutamate, GreenTea Flavor Powder, Combined Flavor(Coolmint Flavor Powder), Combined Flavor(Peppermint Flavor Powder), L-Menthol, Lemon Juice, Aloe Extract Powder, Tea Extract, Hydroxyapatite, Xanthan Gum, Hydroxypropylcellulose, Sodium Bicarbonate, Magnesium Stearate

PURPOSE

Helps protect against cavities and freshen breath.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

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 immediately.
This toothpaste contains 1000ppm of fluorine.
If children under 6 years of age swallowed an over dose, get medical help or contact a Poison Control Center immediately.

USES

for oral use only

INDICATION & USAGE SECTION

Adults and children 6 years of age and older

Literally chew a tablet then brush teeeth thoroughly,
preferably after each meal or at least twice a day, every day,

or as directed by a dentist or physician.
DO NOT swallow a tablet.
Children under 6 years of age: Consult a dentist or doctor.

ORAL PROJEQT O1 TOOTHPASTETABLETS

sodium fluoride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76058-500
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	5 g
SODIUM PYROPHOSPHATE (UNII: O352864B8Z) (PYROPHOSPHORIC ACID - UNII:4E862E7GRQ)	SODIUM PYROPHOSPHATE	1 g
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	0.05 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76058-500-01	62 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	08/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2022	

Labeler - Sungwon Pharmaceutical Co., Ltd. (689787898)

Registrant - Sungwon Pharmaceutical Co., Ltd. (689787898)

Establishment

Name	Address	ID/FEI	Business Operations
Sungwon Pharmaceutical Co., Ltd.		689787898	manufacture(76058-500)

Revised: 8/2022 Sungwon Pharmaceutical Co., Ltd.