

NEED FOR YOU LIMPIO TOOTH- sodium monofluorophosphate paste, dentifrice NEED FOR YOU

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.

ACTIVE INGREDIENT

Sodium Monofluorophosphate 0.76%

INACTIVE INGREDIENTS

Sorbitol, Water, Sodium Cocoyl Glutamate, Cellulose Gum, Glycerin, Menthol, Mentha Piperita (Peppermint) Oil, Mentha Spicata Herb Oil, Herb Flavor, Stevioside, Hydroxyapatite, Xylitol, Citrus Grandis (Grapefruit) Seed Extract, Propolis Wax, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Officinalis (Sage) Leaf Extract, Eucalyptus Globulus Leaf Extract, Aloe Barbadensis Leaf Extract, Taraxacum Officinale (Dandelion) Rhizome, Ascorbic Acid

PURPOSE

Caries prevention

WARNINGS

- Contains 1000ppm of fluoride.
- Do not swallow and rinse mouth thoroughly after use
- If you experience any problems with your gums or mouth during use, discontinue use and consult your doctor.
- For children under 6 years of age, use small amounts of toothpaste. And use it under the supervision of a guardian to avoid sucking or swallowing.
- Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities.
- Keep out of the reach of children under 6 years of age.

KEEP OUT OF REACH OF CHILDREN

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

Uses

- Keep your teeth white and strong.
- Keep your mouth clean.
- Refresh the inside of the mouth.
- Prevents tooth decay caused by fluoride and removes bad breath.
- Increases aesthetic effect.
- Prevention of gingivitis and periodontitis (alveolar fistula)
- Prevention of periodontal disease
- Prevention of gum disease
- Prevention of plaque deposition, removal of plaque (anti-prag)

Directions

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8 1373-0 10
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C8 10JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.91 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Sodium Cocoyl Glutamate (UNII: BMT4RCZ3HG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:8 1373-0 10-02	1 in 1 CARTON	12/01/2020	
1	NDC:8 1373-0 10-01	120 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	12/01/2020	

Labeler - NEED FOR YOU (695126264)**Registrant** - NEED FOR YOU (695126264)**Establishment**

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO., LTD		5578 10721	manufacture(8 1373-0 10)

Revised: 12/2020

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