PRO CARE FLOURIDE- sodium fluoride gel
DILIGO HOLDINGS JOINT STOCK COMPANY

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.

Pro Care Flouride Toothpaste

Drugs Facts:

Active ingredient

Sodium fluoride 0.21%

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

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.

Other information

Use at least 0.04 oz (1 g) of toothpaste. Close the cap after usage. Keep away from direct sunlight for a long time.

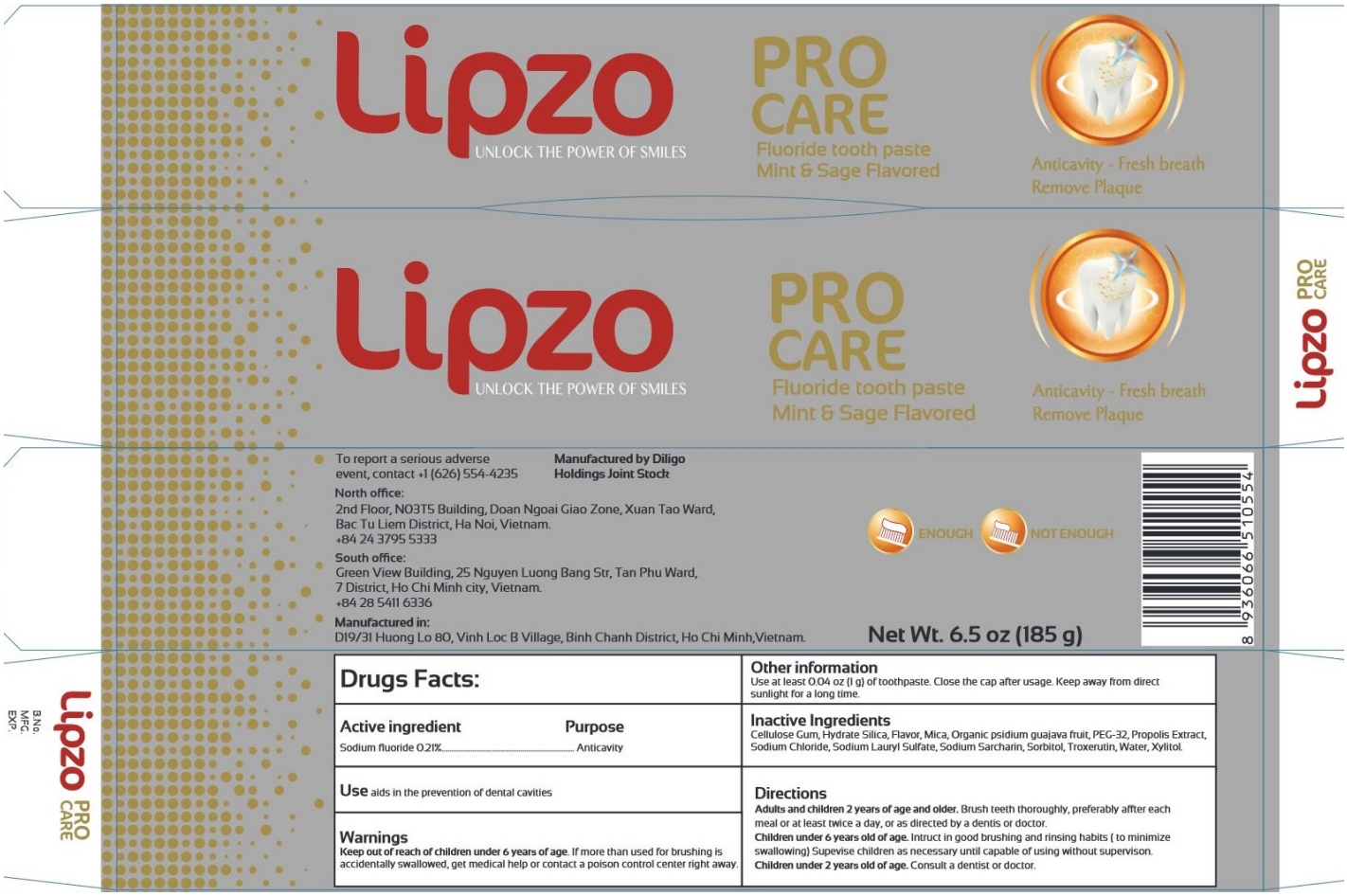
Inactive Ingredients

Cellulose Gum, Hydrate Silica, Flavor, Mica, Organic psidium guajava fruit, PEG-32, Propolis Extract, Sodium Chloride, Sodium Lauryl Sulfate, Sodium Sarcharin, Sorbitol, Troxerutin, Water, Xylitol.

Directions

Adults and 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 dentis or doctor.
Children under 6 years old of age. Intruct in good brushing and rinsing habits (to minimize swallowing) Supevise children as necessary until capable of using without supervison.
Children under 2 years old of age. Consult a dentist or doctor.

Package Labeling:



PRO CARE FLOURIDE

sodium fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78989-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.1 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MICA (UNII: V8A1AW0880)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
TROXERUTIN (UNII: 7Y4N11PXO8)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78989-001-01	1 in 1 BOX	08/05/2020	
1		185 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	08/05/2020	

Labeler - DILIGO HOLDINGS JOINT STOCK COMPANY (555365269)

Revised: 8/2020 DILIGO HOLDINGS JOINT STOCK COMPANY