SYNEDENT FLX- sodium fluoride mouthwash Synedgen Inc.

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.

Synedent FLX 10 oz

Active Ingredients

Sodium fluoride 0.05% (0.02% fluoride ion)

Purpose

Anticavity

Directions

Adults and children 6 years of age and older: Use once a day after brushing your teeth with toothpaste. Vigorously swish 10 milliliters (2 teaspoons) of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Children under 6 years of age: Consult a dentist or doctor.

USE

Aids in the prevention of dental cavities

Warnings

Keep out of reach of children.

If more than indicated is swallowed, get medical attention or contact a Poison Control Center right away. Contains shellfish derivatives. Not to be used by pets. Do not use if safety seal is broken or missing.

Warning

Keep out of reach of children

Inactive Ingredients

Water, Sorbitol, Glycerin, Xylitol, Polysorbate 20, Peppermint Oil, Benzoic Acid, ChitoTek (Chitosan Argininamide), Sodium Hydroxide

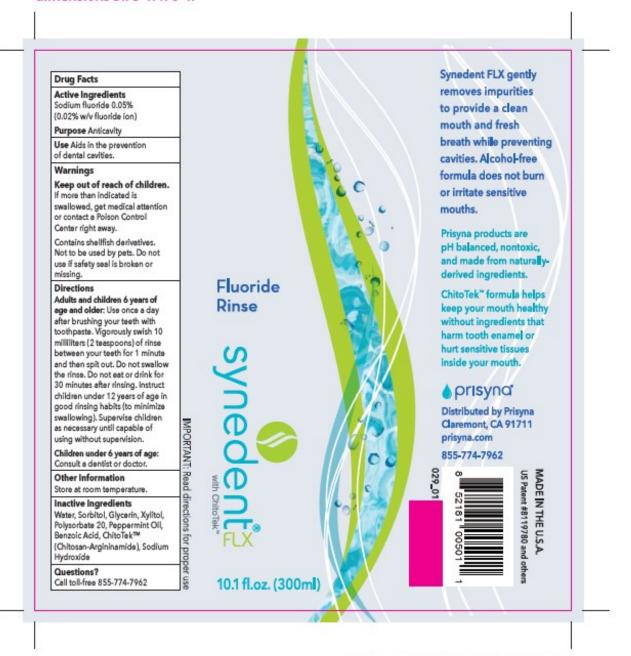
Other Information

Store at room temperature

Question?

Label Sample

dimensions 5.75"w x 6" h



Pink box for Exp date and lot code to be removed from final art Size = 9mm w x 23mm tall

PRINTER - TURN OFF layer with dimensions to remove magenta instructions

SYNEDENT FLX

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42368-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.02 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)	49.882 g in 100 mL	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:42368-005- 01	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/0 1/20 17	

Labeler - Synedgen Inc. (830276353)

Revised: 3/2020 Synedgen Inc.