

**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.*

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**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?**

Call toll-free 855-774-7962

## Label Sample

dimensions 5.75" w x 6" h

<b>Drug Facts</b>
<b>Active Ingredients</b> Sodium fluoride 0.05% (0.02% w/v fluoride ion)
<b>Purpose</b> Anticavity
<b>Use</b> Aids in the prevention of dental cavities.
<b>Warnings</b> <b>Keep out of reach of children.</b> 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.
<b>Directions</b> <b>Adults and children 6 years of age and older:</b> 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. <b>Children under 6 years of age:</b> Consult a dentist or doctor.
<b>Other Information</b> Store at room temperature.
<b>Inactive Ingredients</b> Water, Sorbitol, Glycerin, Xylitol, Polysorbate 20, Peppermint Oil, Benzoic Acid, ChitoTek™ (Chitosan-Argininamide), Sodium Hydroxide
<b>Questions?</b> Call toll-free 855-774-7962

**Fluoride Rinse**

**synedent<sup>FLX</sup>**  
with ChitoTek™

**10.1 fl.oz. (300ml)**

**prisynd**  
Distributed by Prisynd  
Claremont, CA 91711  
prisynd.com  
855-774-7962

**MADE IN THE U.S.A.**  
US Patent #8119780 and others

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**IMPORTANT:** Read directions for proper use

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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42368-005
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0K00R)	49.882 g in 100 mL

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	
<b>Contains</b>			

**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	12/01/2017	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	12/01/2017	

**Labeler** - Synedgen Inc. (830276353)

Revised: 3/2020

Synedgen Inc.