

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 2 oz

Drug Facts

Active Ingredients

Sodium fluoride 0.05% (0.02% fluoride ion)

Purpose Anticavity

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.

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.

Other Information

Store at room temperature.

Inactive Ingredients

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

Question?

Call toll-free 855-774-7962

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Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Labels

Pleasant tasting Alcohol-free


synedent[®] FLX
with ChitoTek™

FLUORIDE RINSE

Freshens breath, cleans teeth and gums, and helps prevent cavities.



2 fl oz (59.1 mL)


synedent[®] FLX

Drug Facts: See the inside label for all Drug Facts.

IMPORTANT: Read directions for proper use.

Directions: Use once a day after brushing. Vigorously swish 2 tsp of rinse between your teeth for 1 minute and then spit out. Do not eat or drink for 30 minutes.

Active Ingredients: Sodium fluoride 0.05% (0.02% w/v fluoride ion)

Inactive Ingredients: Water, Sorbitol, Glycerin, Xylitol, Polysorbate 20, Peppermint Oil, Benzoic Acid, ChitoTek™ (Chitosan-Argininamide), Sodium Hydroxide

Caution: Contains shellfish derivatives.

Storage: Store at room temperature.

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Warning: Not to be used by children under the age of 6 or pets. Do not use if safety seal is broken or missing.

 **prisyna**
Distributed by Prisyna
Claremont, CA 91711
prisyna.com



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

Top layer

Drug Facts**Active Ingredients**

Sodium fluoride 0.05%
(0.02% w/v fluoride ion)

Purpose Anticavity

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.

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

Middle layer
(prints on underside of front layer)

Drug Facts (continued)

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.

Other Information

Store at room temperature.

Inactive Ingredients

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

Questions?

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Claremont, CA 91711
prisyna.com

855-774-7962

Base layer

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:Q80VPU408O)	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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42368-005-00	59.1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/30/2019	

Labeler - Synedgen Inc. (830276353)

Revised: 3/2020

Synedgen Inc.