

**FLUORIDEX- stannous fluoride rinse liquid**  
**DEN-MAT HOLDINGS, LLC**

-----  
**Fluoridex - 0.63% Stannous Fluoride Rinse**

***Active ingredient***

Stannous Fluoride 0.63% Rinse Concentrate

***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 rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Do not swallow the rinse

***Directions***

**Adults and children 6 years of age and older:**

- Do not use before mixing with water
- Use once a day after brushing your teeth with a toothpaste
- Separate provided graduated cup from the mixing cap
- Fill graduated cup to 1/8oz. fill line with Fluoridex Daily Renewal Oral Rinse Concentrate
- Add warm water to 1 oz. fill line
- Place the mixing cap onto the filled cap until it snaps closed
- Shake thoroughly then remove mixing cap
- Use immediately after preparing the rinse
- Vigorously swish with half of the prepared solution between your teeth for 1 minute and then spit out
- Do not swallow the rinse
- Repeat the procedure with the remaining half of the prepared solution
- 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**

- This product may produce surface staining of the teeth
- Adequate toothbrushing may prevent these stains which are harmful or permanent and may be removed by your dentist
- Store at controlled room temperature 15° - 30°C (59° - 86° F)
- See package insert for additional information
- For your protection, do not use if tamper seal on box is broken or missing

***Inactive Ingredients***

Glycerin, Hydrogenated Starch Hydrolysate, Flavor

**Questions or comments?**

Call: 1-800-752-2564

NDC 59883-004-01

FLUORIDEX

DAILY

RENEWAL

Prescription-Strength

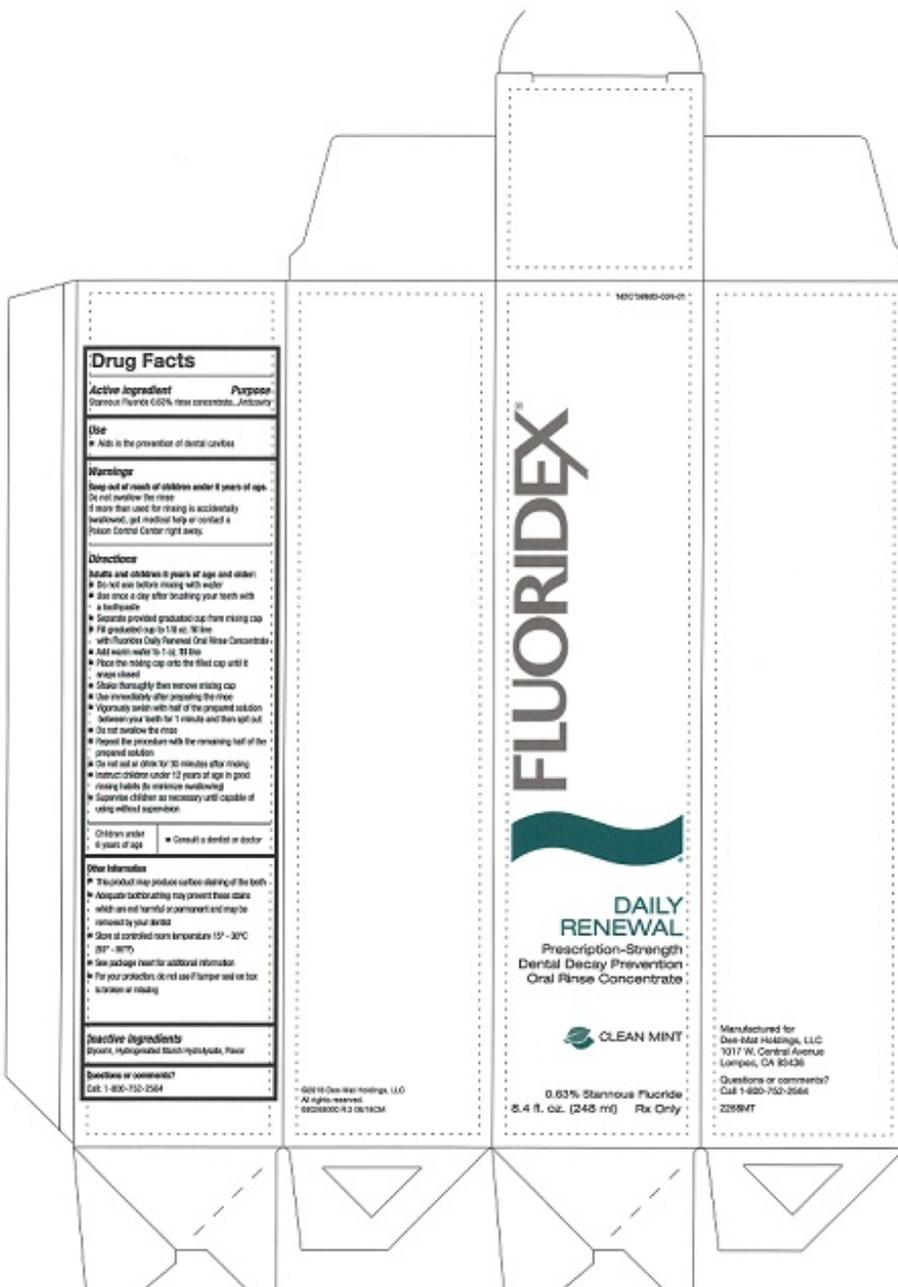
Dental Decay Prevention

Oral Rinse Concentrate

CLEAN MINT

0.63% Stannous Fluoride

8.4 fl. oz. (248 ml) Rx Only



## FLUORIDEX

stannous fluoride rinse liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59883-004
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>STANNOUS FLUORIDE</b> (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.53 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-004-01	1 in 1 BOX	01/11/2016	
1		310 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/11/2016	

**Labeler** - DEN-MAT HOLDINGS, LLC (809857704)

Revised: 11/2023

DEN-MAT HOLDINGS, LLC