

**LUDENT- sodium fluoride tablet, chewable**  
**Sancilio & Company Inc**

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**Ludent® Fluoride Chews**

**Each 0.5 mg Fluoride Tablet Contains:**

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Fluoride (as Sodium Fluoride)*	0.5 mg
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\* Each 0.5 mg Fluoride Tablet contains 0.5 mg Fluoride from 1.1 mg Sodium Fluoride (NaF).

**WARNING**

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IF OVERDOSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY 1-800-222-1222. TABLET SHOULD BE CHEWED. THIS PRODUCT, AS WITH ALL CHEWABLE TABLETS, IS NOT RECOMMENDED FOR CHILDREN UNDER AGE 4 DUE TO RISK OF CHOKING.**

**DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING**

**Directions**

**USE AS DIRECTED BY YOUR PHYSICIAN.**

**Description**

White to off-white, orange flavor, round-shaped chewable tablet debossed "SCI" on one side and "1007" on the other.

**See inside panel for additional information**

**Caution**

Do not use this product if you are allergic to any of the ingredients. Take this product at least 2 hours before or after taking any products containing calcium (including milk, yogurt, other dairy products) or aluminum/magnesium hydroxide (e.g., certain antacids/laxatives). Prolonged daily ingestion of excessive fluoride may result in varying degrees of dental fluorosis. Account for all daily sources of fluoride intake.

**Other Ingredients**

Xylitol, microcrystalline cellulose, malic acid, magnesium stearate, talc, citric acid, natural orange flavor, sucralose.

**Storage**

Store in a cool, dry place at room temperature 20° - 25°C (68° - 77°F) away from heat and sunlight. Store in original container.

This medical food product is formulated to be administered orally, under the ongoing supervision of a physician and is intended for the dietary management of dental caries for which a distinctive nutritional

requirement of fluoride, based on recognized scientific principles, has been established by medical evaluation.

The numeric identifier on this product's labeling is an assigned product code for use with pharmacy-level, health-insurance and state level reimbursement programs and is not intended to denote registration with the FDA.

**Manufactured by: Sancilio & Co., Inc.  
Riviera Beach, FL 33404 USA**

rev. 12/02/11

## PRINCIPAL DISPLAY PANEL - 0.5 mg Bottle Label

**Sancilio &  
Company, Inc.**  
*Developing Good Science into Great Medicine*

44946-1009-9

**Ludent®-Fluoride  
Chews**  
**Sodium Fluoride Chewable Tablets**

NO DYES, ARTIFICIAL FLAVORS OR SUGAR  
SACCHARIN AND GLUTEN FREE  
CONTAINS XYLITOL

**0.5  
mg**

**Dispense under a  
physician's order†**

**Dietary  
Supplement**

**1000 tablets**

**SCI Sancilio & Company, Inc.** 44946-1009-9  
*Developing Good Science into Great Medicine*

**Ludent®-Fluoride Chews**  
Sodium Fluoride Chewable Tablets

NO DYES, ARTIFICIAL FLAVORS OR SUGAR  
SACCHARIN AND GLUTEN FREE  
CONTAINS XYLITOL

**0.5 mg**

**Dispense under a physician's order†**

**Dietary Supplement**

**1000 tablets**

Fluoride (as Sodium Fluoride)	Amount per serving	% Daily Value*
	0.5 mg	

**Supplement Facts**  
Serving Size: 1 Tablet  
Servings per Container: 1000

\*Percent Daily Values (N200) based on a 2000 calorie diet.  
\*\* Daily Value not established.

**Other Ingredients:** Xylitol, microcrystalline cellulose, malic acid, magnesium stearate, talc, citric acid, natural orange flavor, sucralose.  
\*adds negligible amount of sugar

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**Directions: USE AS DIRECTED BY YOUR PHYSICIAN.**

**Description:** White to off-white, orange flavor, round-shaped chewable tablet debossed "SCF" on one side and "1007" on the other.

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**Storage:** Store in a cool, dry place at room temperature 20° - 25°C (68° - 77°F) away from heat and sunlight. Store in original container.

The numeric identifier on this product's labeling is an assigned product code for use with pharmacy-level, health-insurance and state level reimbursement programs and is not intended to denote registration with the FDA.

**†The manufacturer of this product requires that it be dispensed only under the order of a physician or licensed medical practitioner.**

**LOT/EXP**  
NO VARNISH

Manufactured by:  
Sancilio & Company, Inc.  
3824 Fical Court  
Riviera Beach, FL 33404  
(800)501-8711

Made in the USA

REV 09/11/2016

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**LUDENT**

sodium fluoride tablet, chewable

**Product Information**

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:44946-1009
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.5 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Microcrystalline Cellulose</b> (UNII: OPIR32D61U)	
<b>Malic Acid</b> (UNII: 817L1N4CKP)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Anhydrous Citric Acid</b> (UNII: XF417D3PSL)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:44946-1009-3	24 in 1 BOX		
1		120 in 1 BOTTLE		
2	NHRIC:44946-1009-9	12 in 1 BOX		
2		1000 in 1 BOTTLE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
Dietary Supplement		12/20/2011	

**Supplement Facts****Serving Size :** **Serving per Container :**

<b>Amount Per Serving</b>	<b>% Daily Value</b>
color	
scoring	
shape	
size (solid drugs)	13 mm
imprint	
flavor	

