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

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#### Ludent® Fluoride Chews

**Each 0.5 mg Fluoride Tablet Contains:** 

Fluoride (as Sodium 0.5 mg
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#### **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  $20^{\circ}$  -  $25^{\circ}$ C ( $68^{\circ}$  -  $77^{\circ}$ 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

<sup>\*</sup> Each 0.5 mg Fluoride Tablet contains 0.5 mg Fluoride from 1.1 mg Sodium Fluoride (NaF).

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

44946-1009-9

# PRINCIPAL DISPLAY PANEL - 0.5 mg Bottle Label

Sancilio & Company, Inc.

Developing Good Science into Great Medicine

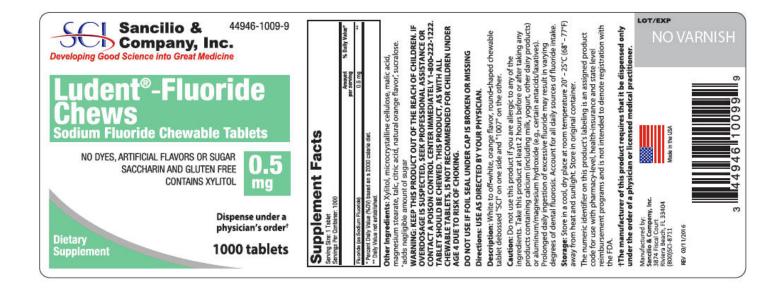
Ludent<sup>®</sup>-Fluoride Chews Sodium Fluoride Chewable Tablets

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

0.5 mg

Dispense under a physician's order<sup>†</sup>

Dietary Supplement 1000 tablets



### **LUDENT**

sodium fluoride tablet, chewable

# **Product Information**

Product TypeDIETARY SUPPLEMENTItem Code (Source)NHRIC:44946-1009

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

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

Inactive Ingredients				
Ingredient Name	Strength			
Xylitol (UNII: VCQ006KQ1E)				
Microcrystalline Cellulose (UNII: OP1R32D61U)				
Malic Acid (UNII: 817L1N4CKP)				
Magnesium Stearate (UNII: 70097M6I30)				
Talc (UNII: 7SEV7J4R1U)				
Anhydrous Citric Acid (UNII: XF417D3PSL)				
Sucralose (UNII: 96K6UQ3ZD4)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
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					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
Dietary Supplement		12/20/2011			

# **Supplement Facts**

Serving Size : Serving per Container :

Amount Per Serving % Daily Value

color

scoring

shape

size (solid drugs) 13 mm

imprint

flavor

# Labeler - Sancilio & Company Inc (176681257)

Revised: 2/2018 Sancilio & Company Inc