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

Ludent® Fluoride Chews

Each 0.25 mg Fluoride Tablet Contains:

Fluoride (as Sodium Fluoride)*	0.25 mg

* **Each 0.25 mg Fluoride Tablet contains 0.25 mg Fluoride from 0.55 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 "6" 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 - 0.25 mg Bottle Label

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

44946-1008-3

Ludent®-Fluoride
Chews
Sodium Fluoride Chewable Tablets

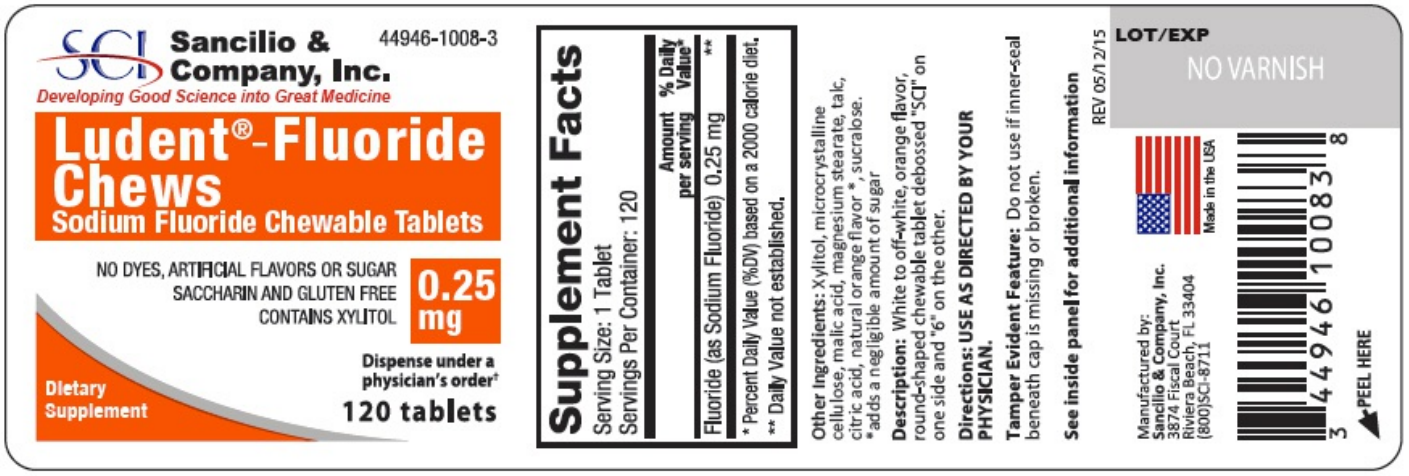
NO DYES, ARTIFICIAL FLAVORS OR SUGAR
SACCHARIN AND GLUTEN FREE
CONTAINS XYLITOL

0.25
mg

Dispense under a
physician's order†

Dietary
Supplement

120 tablets



LUDENT

sodium fluoride tablet, chewable

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:44946-1008
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.25 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:44946-1008-3	24 in 1 BOX		
1		120 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) 11 mm	
imprint	
flavor	

Labeler - Sancilio & Company Inc. (176681257)

Revised: 2/2018 Sancilio & Company Inc.