

**LUDENT- sodium fluoride tablet, chewable**  
**A-S Medication Solutions**

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**Ludent® Fluoride Chews**

**Each 1.0 mg Fluoride Tablet Contains:**

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Fluoride (as Sodium Fluoride)*	1.0 mg
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\* Each 1.0 mg Fluoride Tablet contains 1.0 mg Fluoride from 2.2 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 "4" 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

## Sodium Fluoride



## LUDENT

sodium fluoride tablet, chewable

### Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:50090-3546(NDC:44946-1010)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 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:50090-3546-0	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)	13 mm	
imprint		
flavor		

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3546)