MULTIVITAMIN WITH FLUORIDE- .alpha.-tocopherol acetate, dl-, ascorbic acid, cyanocobalamin, sodium fluoride, folic acid, niacin, pyridoxine, riboflavin, thiamine, vitamin a, and vitamin d tablet, chewable Sancilio & Company Inc

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# Multivitamin with Fluoride Chewable Tablets

# Each Multivitamin with 0.5 mg Fluoride Tablet Contains:

Vitamin A (as Acetate)	2500 IU
Vitamin C	60 mg
Vitamin D	400 IU
Vitamin E	15 IU
Thiamine	1.05 mg
Riboflavin	1.2 mg
Niacin	13.5 mg
Vitamin B6	1.05 mg
Folate (as Folic Acid)	0.3 mg
Vitamin B12	4.5 mcg
Fluoride (as Sodium Fluoride)*	0.5 mg

<sup>\*</sup> Each Multivitamin with 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**

Off-white to pale yellow, speckled, fruit flavor, round-shaped chewable tablet debossed "SCI" on one side and "5" on the other.

#### 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, mannitol, talc, magnesium stearate, sucralose, natural fruit flavor, citric acid.

### 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

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# PRINCIPAL DISPLAY PANEL - 0.5 mg Tablet Bottle Label

Sancilio &

Company, Inc.

Developing Good Science into Great Medicine™

44946-1024-1

Multivitamin with Fluoride Chewable Tablets

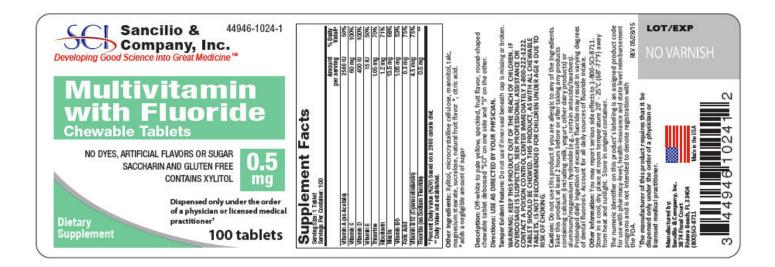
NO DYES, ARTIFICIAL FLAVORS OR SUGAR SACCHARIN AND GLUTEN FREE CONTAINS XYLITOL

0.5 mg

Dispensed only under the order of a physician or licensed medical practitioner†

Dietary Supplement

100 tablets



# MULTIVITAMIN WITH FLUORIDE

.alpha.-tocopherol acetate, dl-, ascorbic acid, cyanocobalamin, sodium fluoride, folic acid, niacin, pyridoxine, riboflavin, thiamine, vitamin a, and vitamin d tablet, chewable

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:44946-1024
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
.AlphaTocopherol Acetate, DL- (UNII: WR1WPI7EW8) (.AlphaTocopherol, DL UNII:7QWA1RIO01)	.AlphaTocopherol, DL-	15 [iU]	
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg	
Cyanocobalamin (UNII: P6 YC3EG204) (Cyanocobalamin - UNII:P6 YC3EG204)	Cyanocobalamin	4.5 ug	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.5 mg	
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.3 mg	
Niacin (UNII: 2679 MF687A) (Niacin - UNII:2679 MF687A)	Niacin	13.5 mg	
Pyridoxine (UNII: KV2JZ1BI6Z) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine	1.05 mg	
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Ribo fla vin	1.2 mg	
Thiamine (UNII: X66NSO3N35) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.05 mg	
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	2500 [iU]	
Vitamin D (UNII: 9 VU1KI44GP) (Vitamin D - UNII:9 VU1KI44GP)	Vitamin D	400 [iU]	

Inactive Ingredients		
Ingredient Name	Strength	
Xylitol (UNII: VCQ006KQ1E)		
Microcrystalline Cellulose (UNII: OP1R32D61U)		
Mannitol (UNII: 3OWL53L36A)		
Talc (UNII: 7SEV7J4R1U)		
Magnesium stearate (UNII: 70097M6I30)		
Sucralose (UNII: 96K6UQ3ZD4)		
Anhydrous Citric acid (UNII: XF417D3PSL)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:44946-1024-1	100 in 1 BOTTLE, PLASTIC		

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:	
	<b>Amount Per Serving</b>	% Daily Value	
color			
scoring	1		
shape			
size (solid drugs)	13 mm		
imprint			
flavor			

# Labeler - Sancilio & Company Inc (176681257)

Revised: 3/2018 Sancilio & Company Inc