

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

Multivitamin with Fluoride
Chewable Tablets

Each Multivitamin with 1.0 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)*	1.0 mg

* Each Multivitamin with 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

Off-white to pale yellow, speckled, fruit flavor, round-shaped chewable tablet debossed "SCI" on one side and "3" 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

rev. 11/18/11

PRINCIPAL DISPLAY PANEL - 1.0 mg Tablet Bottle Label

**Sancilio &
Company, Inc.**

Developing Good Science into Great Medicine™

44946-1025-1

**Multivitamin
with Fluoride
Chewable Tablets**

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

**1.0
mg**

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

**Dietary
Supplement**

100 tablets

Multivitamin with Fluoride Chewable Tablets

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

1.0 mg

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

Dietary Supplement

100 tablets

Supplement Facts

	Amount per serving	% Daily Value*
Vitamin A (as Acetate)	2500 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	15 IU	50%
Thiamine	1.05 mg	70%
Riboflavin	1.2 mg	71%
Niacin	13.5 mg	68%
Vitamin B6	1.05 mg	58%
Vitamin B12 (Cyanocobalamin)	0.3 mg	75%
Sodium Fluoride	4.5 mg	75%
Fluoride (as Sodium Fluoride)	1.0 mg	100%

*Percent Daily Values (NDV) based on a 2000 calorie diet.
 *Daily value not established.

Other ingredients: Xylitol, microcrystalline cellulose, mannitol, talc, magnesium stearate, sucralose, natural fruit flavor*, citric acid.
 *adds a negligible amount of sugar

Description: Off-white to pale yellow, speckled, fruit flavor, round-shaped chewable tablet debossed "SCI" on one side and "3" on the other.
 Directions: USE AS DIRECTED BY YOUR PHYSICIAN.
 Tamper Evident Feature: Do not use if inner seal beneath cap is missing or broken.
 WARNING: KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IF OVERDOSSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT POISON CONTROL AT 1-800-368-5773.
 TABLETS SHOULD BE CHEWED. THIS PRODUCT, AS WITH ALL CHEWABLE TABLETS, IS NOT RECOMMENDED FOR CHILDREN UNDER AGE 4 DUE TO RISK OF CHOKING.

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 iron. Prolonged daily ingestion of excessive fluoride may result in varying degrees of dental fluorosis. Account for all daily sources of fluoride intake.
 Other Information: You may report serious side effects to 1-800-SCI-8711. 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 licensure databases. It 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.
 3874 Fiscal Court
 Riviera Beach, FL 33404
 (800) SCI-8711

REV 01/2016

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:44946-1025
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.Alpha.-Tocopherol Acetate, DL- (UNII: WR1WPI7EW8) (.Alpha.-Tocopherol, DL - UNII:7QWA1RIO01)	.Alpha.-Tocopherol, DL-	15 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	4.5 ug
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	1 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.3 mg
Niacin (UNII: 2679MF687A) (Niacin - UNII:2679MF687A)	Niacin	13.5 mg
Pyridoxine (UNII: KV2JZ1B16Z) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine	1.05 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	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: 9VU1K144GP) (Vitamin D - UNII:9VU1K144GP)	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: 70097M6I3O)	
Sucralose (UNII: 96K6UQ3ZD4)	
Anhydrous Citric acid (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:44946-1025-1	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 :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	13 mm	
imprint		
flavor		

Labeler - Sancilio & Company Inc (176681257)

Revised: 3/2018

Sancilio & Company Inc