

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
A-S Medication Solutions

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

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

* 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**

rev. 11/18/11

HOW SUPPLIED

Product: 50090-0435

NDC: 50090-0435-1 100 TABLET, CHEWABLE in a BOTTLE, PLASTIC

.Alpha.-Tocopherol Acetate, DL-, Ascorbic Acid, Cyanocobalamin, Sodium Fluoride, Folic Acid, Niacin, Pyridoxine, Riboflavin, Thiamine, Vitamin A, and Vitamin D



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	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50090-0435(NDC:44946-1024)
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	0.5 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: 9VU1KI44GP) (VITAMIN D - UNII:9VU1KI44GP)	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: 70097M6B0)	
Sucralose (UNII: 96K6UQ3ZD4)	
Anhydrous Citric acid (UNII: XF417D3PSL)	

Product Characteristics

Color	WHITE (Off-white to pale yellow speckled)	Score	no score
Shape	ROUND	Size	13mm
Flavor	FRUIT	Imprint Code	SCI;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-0435-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/20/20 11	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		8300 16429	RELABEL(50090-0435)

Revised: 10/2017

A-S Medication Solutions