

MVC- sodium fluoride, vitamin a palmitate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable
Sancilio & Company Inc

**MULTIVITAMIN WITH FLUORIDE
CHEWABLE TABLETS**

Rx only

Nutrition Facts				
Serving Size 1 Chewable Tablet				
Serving Per Container 30 or 90				
Amount Per Serving (1 Chewable Tablet)	1.0 mg	0.5 mg	0.25 mg	%DV Adults & Children 4 Years or More
Vitamin A	2500 IU	2500 IU	2500 IU	50%
Vitamin C	60 mg	60 mg	60 mg	100%
Vitamin D	400 IU	400 IU	400 IU	100%
Vitamin E	15 IU	15 IU	15 IU	50%
Thiamin	1.05 mg	1.05 mg	1.05 mg	70%
Riboflavin	1.2 mg	1.2 mg	1.2 mg	70%
Niacin	13.5 mg	13.5 mg	13.5 mg	68%
Vitamin B6	1.05 mg	1.05 mg	1.05 mg	53%
Folate	0.3 mg	0.3 mg	0.3 mg	75%
Vitamin B12	4.5 mcg	4.5 mcg	4.5 mcg	75%
Fluoride	1.0 mg	0.5 mg	0.25 mg	*

* Daily Value (%DV) not established

Active ingredients

Fluoride as sodium fluoride.

Other Ingredients

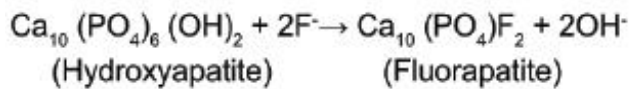
Xylitol, microcrystalline cellulose, mannitol, talc, magnesium stearate, sucralose, natural flavors, citric acid.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Multivitamin with Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a topical as well as systemic source of fluoride.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the hydroxyapatite in the tooth as it forms to produce the more caries-resistant crystal, fluorapatite. The reaction may be expressed by the equation:



Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with fluoride and ten essential vitamins.

Multivitamin with 1.0 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.

Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with Fluoride Chewable Tablets supply significant amounts of vitamins A, C, D, E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Children using Multivitamin with Fluoride Chewable Tablets regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

WARNING

Keep this and all medication out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Should be chewed. This product, as with all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTIONS

The suggested dose of Multivitamin with Fluoride Chewable Tablets should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing Multivitamin with Fluoride Chewable Tablets:

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed.

HOW SUPPLIED

Multivitamin with 1.0 mg, 0.5 mg and 0.25 mg Fluoride Chewable Tablets are all available in 30 and 90 tablet bottles.

STORAGE

Store in a cool dry place. Protect from light and moisture.

Manufactured by:
Sancilio & Company, Inc.
3874 Fiscal Court #200
Riviera Beach, FL 33404

PRINCIPAL DISPLAY PANEL - 1.0 mg Bottle Label

44946-1014-5

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

MVC™-Fluoride 1.0mg*
Multivitamin Chewable Tablets with Fluoride

No dyes, artificial flavors or sugar

Dietary
Supplement

90 tablets
Made in the U.S.A.



Each Chewable Tablet contains:

Vitamin A	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	0.3 mg
Vitamin B12	4.5 mcg
Fluoride	1.0 mg

Description: Off-white to pale yellow, speckled, or orange flavored, hexagon shaped chewable tablet. Debossed "SCI" on one side and "1003" on the other. **Active Ingredient:** Fluoride as Sodium Fluoride (NaF) 2.2 mg. **In active ingredients:** Xylitol, microcrystalline cellulose, malic acid, citric acid, talc, magnesium stearate, natural orange flavor, sucralose.

Dosage and Administration: One tablet daily. Dissolve in mouth or chew before swallowing, preferably at bedtime after brushing teeth. **Overdosage:** Prolonged daily ingestion of excessive fluoride will result in varying degrees of fluorosis.

Caution: Do not eat or drink dairy products within one hour of fluoride administration. **WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.** This product is not recommended for children under age 4. **Adverse Reaction:** Allergic rash and other idiosyncrasies have been rarely reported. **Storage:** Store in a cool, dry place at a controlled room temperature, 20° - 25°C (68° - 77°F) excursions permitted to 15° - 30°C (59° - 86°F). Store in original container. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF. All prescription substitutions using this product shall be pursuant to state statutes as applicable.

This is not an Orange Book product

Lot No:
Exp Date:

Manufactured by: Sancilio & Company, Inc.
3874 Fiscal Court
Riviera Beach, FL 33404

Patent Pending



PRINCIPAL DISPLAY PANEL - 0.5mg Bottle Label

SCI

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

44946-1013-5

Rx Only

MVC® Fluoride

0.5mg *

MULTIVITAMIN WITH FLUORIDE CHEWABLE TABLETS

NO DYES, ARTIFICIAL FLAVORS OR SUGAR
SACCHARIN AND GLUTEN FREE

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

90 Tablets

Made in the U.S.A.

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

44946-1013-5
Rx Only

MVC® Fluoride **0.5mg***
MULTIVITAMIN WITH FLUORIDE CHEWABLE TABLETS

NO DYES, ARTIFICIAL FLAVORS OR SUGAR
SACCHARIN AND GLUTEN FREE

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

90 Tablets
Made in the U.S.A.

Should be chewed. This product, as with all chewable tablets, is not recommended for children under age 4 due to risk of choking.

Nutrition Facts
Serving Size 1 Chewable Tablet
Serving Per Container 90

Amount Per Serving (1 Chewable Tablet)	% Daily Value Adults & Children 4 Years or More
Vitamin A	2500 IU 50%
Vitamin C	60 mg 100%
Vitamin D	400 IU 100%
Vitamin E	15 IU 50%
Thiamin	1.05 mg 70%
Riboflavin	1.2 mg 70%
Niacin	13.5 mg 68%
Vitamin B6	1.05 mg 53%
Folate	0.3 mg 75%
Vitamin B12	4.5 mcg 75%
Fluoride	0.5 mg **

** Daily Value not established

WARNING: Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

See package insert for dosage information and complete listing of ingredients.

Active Ingredients:
Fluoride as sodium fluoride.*

Manufactured by:
Sancilio & Company, Inc.
3874 Fiscal Court #200
Riviera Beach, FL 33404
Patent Pending

LOT/EXP NO VARNISH

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Rev. 11/12/10

PRINCIPAL DISPLAY PANEL - 0.25mg Bottle Label

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

44946-1012-5

Rx Only

MVC® Fluoride

0.25mg *


MULTIVITAMIN WITH FLUORIDE CHEWABLE TABLETS

NO DYES, ARTIFICIAL FLAVORS OR SUGAR
SACCHARIN AND GLUTEN FREE

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

90 Tablets

Made in the U.S.A.


44946-1012-5
Rx Only
Sancilio & Company, Inc.
Developing Good Science into Great Medicine

MVC[®] Fluoride 0.25mg*
MULTIVITAMIN WITH FLUORIDE CHEWABLE TABLETS

NO DYES, ARTIFICIAL FLAVORS OR SUGAR
 SACCHARIN AND GLUTEN FREE

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

90 Tablets
 Made in the U.S.A.

Nutrition Facts
 Serving Size 1 Chewable Tablet
 Serving Per Container 90

Amount Per Serving (1 Chewable Tablet)	% Daily Value Adults & Children 4 Years or More
Vitamin A	2500 IU 50%
Vitamin C	60 mg 100%
Vitamin D	400 IU 100%
Vitamin E	15 IU 50%
Thiamin	1.05 mg 70%
Riboflavin	1.2 mg 70%
Niacin	13.5 mg 68%
Vitamin B6	1.05 mg 53%
Folate	0.3 mg 75%
Vitamin B12	4.5 mcg 75%
Fluoride	0.25 mg **

** Daily Value not established


WARNING: Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

See package insert for dosage information and complete listing of ingredients.

Active Ingredients:
 Fluoride as sodium fluoride.*

Manufactured by:
Sancilio & Company, Inc.
 3874 Fiscal Court #200
 Riviera Beach, FL 33404
 Patent Pending

NO VARNISH



3 44946 10125 5

Rev. 11/12/10

MVC

sodium fluoride, vitamin a palmitate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:44946-1014
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
Vitamin A Palmitate (UNII: 1D1K0N0VVC) (Vitamin A - UNII:81G40H8B0T, Retinol - UNII:G2SH0XKK91)	Vitamin A	2500 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	15 [iU]
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.05 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.2 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	13.5 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	1.05 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.3 mg
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Malic Acid (UNII: 817L1N4CKP)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xylitol (UNII: VCQ006KQ1E)	
Talc (UNII: 7SEV7J4R1U)	

Magnesium Stearate (UNII: 70097M6I30)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:44946-1014-4	4 in 1 BOX		
1		24 in 1 BOX		
1		30 in 1 BOTTLE		
2	NHRIC:44946-1014-5	4 in 1 BOX		
2		24 in 1 BOX		
2		90 in 1 BOTTLE		
3	NHRIC:44946-1014-6	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		12/20/2009	

Supplement Facts

Serving Size : Serving per Container :

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	12 mm	
imprint		
flavor		

MVC

sodium fluoride, vitamin a palmitate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:44946-1013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.5 mg
Vitamin A Palmitate (UNII: 1D1K0N0VVC) (Vitamin A - UNII:81G40H8B0T, Retinol - UNII:G2SH0XKK91)	Vitamin A	2500 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg

Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	15 [iU]
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.05 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.2 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	13.5 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	1.05 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.3 mg
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Malic Acid (UNII: 817L1N4CKP)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xylitol (UNII: VCQ006KQ1E)	
Talc (UNII: 7SEV7J4R1U)	
Magnesium Stearate (UNII: 70097M6I30)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:44946-1013-4	4 in 1 BOX		
1		24 in 1 BOX		
1		30 in 1 BOTTLE		
2	NHRIC:44946-1013-5	4 in 1 BOX		
2		24 in 1 BOX		
2		90 in 1 BOTTLE		
3	NHRIC:44946-1013-6	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		12/20/2009	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	12 mm	
imprint		

flavor

MVC

sodium fluoride, vitamin a palmitate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:44946-1012
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
Vitamin A Palmitate (UNII: 1D1K0N0VVC) (Vitamin A - UNII:81G40H8B0T, Retinol - UNII:G2SH0XKK91)	Vitamin A	2500 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	15 [iU]
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.05 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.2 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	13.5 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	1.05 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.3 mg
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Malic Acid (UNII: 817L1N4CKP)	
Microcrystalline Cellulose (UNII: OPIR32D61U)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xylitol (UNII: VCQ006KQ1E)	
Talc (UNII: 7SEV7J4R1U)	
Magnesium Stearate (UNII: 70097M6I30)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:44946-1012-7	7 in 1 BOTTLE, PLASTIC		
2	NHRIC:44946-1012-4	4 in 1 BOX		
2		24 in 1 BOX		
2		30 in 1 BOTTLE		
3	NHRIC:44946-1012-5	4 in 1 BOX		
3		24 in 1 BOX		
3		90 in 1 BOTTLE		

4 | NHRIC:44946-1012-6

30 in 1 BLISTER PACK

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		12/20/2009	

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)

Establishment

Name	Address	ID/FEI	Business Operations
Sancilio & Company Inc		080018491	MANUFACTURE, RELABEL, REPACK

Revised: 2/2018

Sancilio & Company Inc