

TRI-VITAMIN WITH FLUORIDE- vitamin a, ascorbic acid, vitamin d, and sodium fluoride solution/ drops
Sancilio & Company Inc

Tri-Vitamin Drops with Fluoride

Ingredients

Vitamin A	1500 IU
Vitamin C	35 mg
Vitamin D	400 IU
Fluoride* (as Sodium Fluoride)	0.25 mg

* Each 1 mL of Tri-Vitamin Drops contains 0.25 mg Fluoride from 0.55 mg Sodium Fluoride (NaF).

Other Ingredients:

Glycerin, water, polysorbate 80, sodium hydroxide, propylene glycol, sucralose, fruit flavor, methyl paraben, caramel color, propyl paraben.

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.

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.

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) since these may decrease effectiveness.

Prolonged daily ingestion of excessive fluoride may result in varying degrees of dental fluorosis.

This medical food product is formulated to be administered orally, under the 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. This product is a medical food and is not intended to be used as a drug or dietary supplement.

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.

SHAKE WELL BEFORE USING

DIRECTIONS

Use as directed by a physician.

How to Use

Fill dropper to appropriate line and dispense with a single squeeze of the dropper bulb. The full dose will be given. It is normal for a small amount to remain in the tip of the dropper.

Do not accept if tamper evident box seal is broken or missing.

Manufactured by: Sancilio & Co., Inc. Riviera Beach, FL 33404 USA

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

44946-1035-8

SCI

Sancilio &

Company, Inc.

Developing Good Science into Great Medicine

Tri-Vitamin Drops with Fluoride

VITAMINS A, C, D & FLUORIDE DROPS

NO DYES OR SUGAR

SACCHARIN AND GLUTEN FREE

0.25

mg/mL

1 2/3 FL. OZ. (50 mL)

**Dispense under a
physician's order†**

Dietary

Supplement

SCI Sancilio & Company, Inc. 44946-1035-8
Developing Good Science into Great Medicine

**Tri-Vitamin Drops
with Fluoride**

VITAMINS A, C, D & FLUORIDE DROPS
NO DYES OR SUGAR
SACCHARIN AND GLUTEN FREE

**0.25
mg/mL**

1 2/3 FL. OZ. (50 mL)

**Dietary
Supplement**

**Dispense under a
physician's order†**

	Amount per serving	% Daily Value*
Vitamin A	1500 IU	30%
Vitamin C	35 mg	58%
Vitamin D	400 IU	100%
Fluoride (as Sodium Fluoride)	0.25 mg	**

* Percent Daily Value (%DV) based on a 2000 calorie diet.
** Daily Value not established.

Other Ingredients: Glycerin, water, polysorbate 80, sodium hydroxide, propylene glycol, sucralose, fruit flavor, methyl paraben, caramel color and propyl paraben.
WARNING: KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IF OVERDOSE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY 1-800-222-1222.

SHAKE WELL BEFORE USE

Directions: Use as directed by a physician
How to Use: Fill dropper to appropriate line AS INSTRUCTED BY YOUR PHYSICIAN and dispense with a single squeeze of the dropper.

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.

The manufacturer of this product requires that it be dispensed only under the order of a physician or licensed medical practitioner.

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 & Company, Inc.
3874 Fiscal Court
Riviera Beach, FL 33404
(800)SCI-8711
REV 10/15/14

Made in the USA

44946 10358 7

TRI-VITAMIN WITH FLUORIDE

vitamin a, ascorbic acid, vitamin d, and sodium fluoride solution/ drops

Product Information

Product Type

DIETARY SUPPLEMENT

Item Code (Source)

NHRC:44946-1035

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	1500 [iU] in 1 mL
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	35 mg in 1 mL
Vitamin D (UNII: 9VU1KI44GP) (Vitamin D - UNII:9VU1KI44GP)	Vitamin D	400 [iU] in 1 mL
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Sodium hydroxide (UNII: 55X04QC32I)	
Propylene glycol (UNII: 6DC9Q167V3)	
Sucralose (UNII: 96K6UQ3ZD4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:44946-1035-8	1 in 1 CARTON		
1		50 mL 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	
flavor	

Labeler - Sancilio & Company Inc (176681257)